SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2004,

or

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to .

Commission file number 0-19825

SciClone Pharmaceuticals, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**94-3116852**
(State or other jurisdiction of Incorporation or organization)	*(I.R.S. Employer Identification No.)*
901 Mariner's Island Boulevard San Mateo, California	**94404**
(Address of principal executive offices)	*(Zip Code)*

(650) 358-3456
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:
None

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $0.001 par value
(Title of Class)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes [X] No [ ]

The aggregate market value of the voting stock held by non-affiliates of the Registrant was approximately $221,926,033 as of June 30, 2004, based upon the closing sale price of the Registrant's Common Stock on The NASDAQ National Market on such date. Shares of Common Stock held by each executive officer and director have been excluded from the calculation because such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 9, 2005, there were 44,696,701shares of the Registrant's Common Stock outstanding.

Part III incorporates by reference from the definitive proxy statement for the Registrant's 2005 Annual Meeting of Stockholders to be filed with the Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form.

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As used in this Annual Report, the terms "we," "us," "our," the "Company" and "SciClone" mean SciClone Pharmaceuticals, Inc. and its subsidiaries (unless the context indicates a different meaning). SciClone, the SciClone logo and ZADAXIN are registered U.S. trademarks and SCV-07 is a trademark of SciClone Pharmaceuticals, Inc. All other Company names and trademarks included in this Annual Report are trademarks, registered trademarks or trade names of their respective owners.

NOTE REGARDING FORWARD-LOOKING STATEMENTS:

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements are based on our current expectations, estimates and projections about our business, industry, management's beliefs and certain assumptions made by us. Words such as "anticipate," "expect," "intend," "plan," "believe" or similar expressions are intended to identify forward-looking statements including those statements we make regarding our future financial results; anticipated product sales and net sales and levels; the timing and outcome of clinical trials and the timing of reporting of clinical trial results; the timing of enrollment, treatment and follow-up for our clinical trials; the prospects for and the preparation status of our Japanese New Drug Application; the preparation and timing of our potential New Drug Applications in the United States; projected increases in the number of hepatitis C patients seeking treatment and re-treatment; ZADAXIN's ability to complement existing therapies; prospects for ZADAXIN and our plans for its enhancement and commercialization; future marketing efforts and their effect on the Company's value; our ability to expand our product pipeline; partnering prospects for ZADAXIN; research and development and other expense levels; future inventory levels; levels of gross margin and cost of product sales and the allocation of financial resources to certain trials and programs. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict. Therefore, our actual results could differ materially and adversely from those expressed in any forward-looking statements as a result of various factors including, but not limited to, those described under the caption "Risk Factors" in this Annual Report on Form 10-K. We undertake no obligation to revise or update publicly any forward-looking statements for any reason.

PART I

Item 1. *Business*

OVERVIEW

SciClone Pharmaceuticals, Inc. is a biopharmaceutical company engaged in the development and commercialization of therapeutics to treat life-threatening diseases. Our lead product ZADAXIN® is currently being evaluated in two phase 3 hepatitis C virus (hepatitis C or HCV) clinical trials in the United States and we expect to report data from both trials by the early part of 2006. ZADAXIN is also being evaluated in other late-stage clinical trials for the treatment of hepatitis B virus (hepatitis B or HBV) and certain cancers. Our other proprietary drug development candidate is SCV-07, which is currently in pre-clinical studies for the treatment of viral and other infectious diseases. We expect to file an Investigational New Drug (IND) application for SCV-07 in the first half of 2005.

ZADAXIN currently is approved for sale in over 30 countries internationally, primarily in Asia, the Middle East and Latin America, and is marketed through our wholly-owned subsidiary SciClone Pharmaceuticals International Ltd. (SPIL). In 2004, revenues from the sale of ZADAXIN totaled $22,765,000, of which 91% were to China.

SciClone Pharmaceuticals, Inc. was organized in 1990 as a California corporation and reincorporated in Delaware in 2003. Our corporate headquarters are located in San Mateo, California. For information about our revenues from external customers, measures of our profit and loss, our total assets and other financial matters, you should read our Consolidated Financial Statements provided in Part II, Item 8 of this Form 10-K.

STRATEGY

Our goal is to develop and commercialize therapeutics targeting indications that represent significant unmet market needs. To meet this objective, our strategy focuses on developing and commercializing our lead product ZADAXIN, expanding our product pipeline, and selectively building our international sales capabilities. Our specific near-term strategic objectives include the following:

- **Secure Regulatory Approvals for ZADAXIN.** We expect to report data from our two phase 3 HCV clinical trials by the early part of 2006 and, if the data are favorable, submit a New Drug Application (NDA) to the Food and Drug Administration (FDA) by the end of 2006. We anticipate that our European marketing and development partner Sigma-Tau would use these data for an NDA submission to the European Medicines Agency (EMEA). In addition to addressing and gaining access to major pharmaceutical markets, we believe that an approval in the United States or Europe would increase ZADAXIN sales in international markets where the drug is currently approved and facilitate approvals in additional international markets.

- **Achieve Broad Penetration of the Hepatitis C Market.** We estimate the worldwide market for HCV therapeutics will grow from approximately $3 billion in 2004 to over $8 billion in 2012. To ensure broad market penetration, we are developing a marketing strategy that could include partnering with other pharmaceutical companies.

- **Develop Product Pipeline.** We intend to expand our product pipeline by developing SCV-07 and a pegylated form of ZADAXIN. We expect to file an IND application for SCV-07 in the first half of 2005. In addition, we are pursuing opportunities to in-license or acquire other product candidates.

- **Selectively Build International Sales Capabilities.** Currently approved for sale in over 30 countries internationally, ZADAXIN generated sales revenues of $22,765,000 in 2004, of which 91% were to China. As one of the few emerging biopharmaceutical companies with successful sales operations, we believe we can leverage our expertise by adding new products to increase international sales. With our existing team of approximately 90 medical representatives in China who have strong relationships with leading physicians in the country, we believe we could effectively and efficiently market other products, in addition to ZADAXIN, without incurring a significant incremental cost.

SciClone's Lead Product ZADAXIN

ZADAXIN is a pure synthetic preparation of thymosin alpha 1, generically referred to as thymalfasin, a natural substance that circulates in the body and is instrumental in the immune response to viral infections and certain cancers. After the administration of a single, standard 1.6 mg subcutaneous dosage of ZADAXIN, the circulating levels of thymosin alpha 1 are temporarily increased 50 to 100 times its normal level in the body. Published scientific and clinical studies have shown that ZADAXIN helps stimulate and direct the body's immune response to eradicate HCV, HBV, other infectious diseases and certain cancers. ZADAXIN has not produced any reported significant side effects or toxicities.

ZADAXIN elicits a variety of immune system responses against viruses and cancer cells. One such response is an increase in white blood cell production and their differentiation into CD-4 helper-cells, specifically towards differentiation of T helper 1 cells (Th1 cells secrete cytokines such as interleukin-2 (IL-2) and gamma interferon). Studies have shown that a Th1-directed immune response is fundamental to the eradication of certain viral diseases, such as HCV and HBV as well as certain cancers. Moreover, as ZADAXIN increases Th1 cells, it also decreases production of Th2 cytokines, such as IL-4, which are associated with persistence of viral infection.

Similarly, ZADAXIN helps increase the production of CD-8 and NK, or natural killer, cells that are able to directly attack and kill virally-infected and certain cancer cells. In addition, ZADAXIN has recently been shown to stimulate the "innate" immune system through effects on Toll-like receptors (TLRs). Both of these activities are important in mounting an effective immune response to an HCV infection. Moreover, ZADAXIN reduces T-cell apoptosis, or programmed cell death, which allows these beneficial cells to circulate for a longer period of time. ZADAXIN also exhibits direct antiviral effects by enhancing the expression of surface-marker proteins (antigens) on virally-infected and certain cancer cells. These surface markers help the body's immune system recognize and target both virally infected and cancer cells for eradication.

Hepatitis C: The Need for Improved Therapeutic Options

HCV is one of the world's most prevalent blood borne chronic infectious diseases and causes inflammation of the liver, which can eventually lead to fibrosis, cirrhosis and hepatocellular carcinoma or liver cancer. The World Health Organization estimates that 170 million people worldwide are infected with HCV. In the United States, 2.7 million people are chronically infected with HCV, according to the Centers for Disease Control and Prevention.

We estimate that the worldwide market for HCV therapies could grow from approximately $3 billion in 2004 to over $8 billion in 2012. This projection is based on an expected significant increase in the number of patients seeking treatment for the first time or re-treatment after failing therapy. Most carriers contracted HCV before blood screening for the virus was developed in 1990. Once a person is infected with HCV, 20 years or more can pass before life-threatening complications from liver damage arise. Due to these factors, the number of individuals diagnosed with HCV and seeking treatment for the first time is expected to increase and reach a peak in 2010. Since approximately 50% of patients fail current HCV therapies, the number of patients seeking re-treatment is also expected to increase.

HCV is a systemic disease localized in the liver, and for the majority of patients, can lead to serious complications, including cirrhosis of the liver, liver failure and hepatocellular carcinoma or liver cancer. Most people are unaware that they are infected with the disease because early symptoms, if present at all, are typically mild and nonspecific. The disease progresses slowly, and consequently it can be up to 20 years after infection before a patient is diagnosed with HCV, at which point serious deterioration of liver function is already typically observed. The American Liver Foundation estimates that the number of deaths in the United States caused by HCV is currently between 8,000 and 10,000 annually and may increase to 30,000 annually in the next ten to twenty years.

Although there is currently no vaccine available to prevent HCV, interferon alpha (both in its standard and pegylated formulations) and ribavirin are approved for the treatment of the disease. Interferon alpha can be used alone as a monotherapy or in combination therapy with ribavirin, but studies show that ribavirin is only effective in combination with interferon alpha. Many patients cannot tolerate the serious side effects and toxicities associated with either or both interferon alpha or ribavirin and often require dose reductions or even early termination of therapy. The current standard of care typically consists of a 48-week treatment of pegylated interferon alpha, most often with ribavirin, followed by a 24-week follow-up observation to determine sustained virologic response (SVR). SVR is defined as the absence of HCV RNA from the bloodstream, measured by qualitative tests such as polymerase chain reaction (PCR) 24 weeks after the completion of 48 weeks of therapy. Patients who achieve an SVR are typically considered to be cured of HCV.

A patient's response to therapy varies based on the viral load, genotype (strain) of the virus, presence of cirrhosis of the liver and ethnicity. There are at least 6 different major genotypes present worldwide, with genotype 1 being the most common in the major pharmaceutical markets of the United States, Europe and Japan. Approximately 75% of HCV carriers in the United States are infected with the genotype 1 strain of the virus, according to the National Institutes of Health. Unfortunately, genotype 1 patients are the least likely to respond to current therapy. For naïve patients (those who have never received therapy), only 41% of patients infected with genotype 1 will achieve an SVR after therapy with pegylated interferon alpha and ribavirin. This compares to 75% of the much fewer patients with genotypes 2 through 6, and 52% of all patients. However, response rates according to genotype vary widely between ethnic groups. For example, among Hispanic patients the response rate for genotype 2 patients is as low as that of the genotype 1 patients. The following chart comprised of information obtained from package insert information for pegylated interferon alpha and ribavirin, summarizes the SVR rates by genotype:

Naïve Patients (n=511)	**% of Patients**	**Response Rate (SVR)**
Genotype 1	75%	41%
Genotypes 2-6	25%	75%
All Genotypes	100%	52%

Source: Package insert information, pegylated interferon and ribavirin

Once a naïve patient fails to respond to therapy, he or she is commonly referred to as a non-responder and is even less likely to respond to re-treatment with current therapy. A non-responder patient's response rate to re-treatment varies based on the viral load, genotype, type and length of prior therapy (interferon alpha/pegylated interferon alpha monotherapy or interferon alpha/pegylated interferon alpha in combination therapy with ribavirin), presence of cirrhosis of the liver and ethnicity. Given the large proportion of genotype 1 patients and their relatively low response to therapy, the vast majority of non-responders consist of genotype 1 patients.

Re-treatment of non-responders with current therapy has a low rate of success. Among the factors affecting response rates are the patients' ability to tolerate ribavirin or endure the full dose of pegylated interferon alpha. For example, ribavirin intolerant patients re-treated with pegylated interferon alpha are unlikely to achieve an SVR. Lowering the dosage of pegylated interferon alpha lowers the chances of an SVR. In treatment with pegylated interferon alpha and ribavirin, 9% of patients who can tolerate only a low dose of pegylated interferon alpha, defined as less than 80% of the recommended dose, achieve an SVR, compared to 17% of patients able to tolerate a full dose, 80% to 100% of the recommended dose of pegylated interferon alpha.

Genotype 1 Non-Responders (to previous therapy of interferon alpha with or without ribavirin)	Response Rate (SVR)
All (n=939)	14%
Re-treated with pegylated interferon alpha without ribavirin (n=70)	0%
Re-treated with low dose (<80%) pegylated interferon alpha and with ribavirin (n=222)	9%
Re-treated with full dose (>80%) pegylated interferon alpha and with ribavirin (n=647)	17%

Source: Shiffman, Mitchell L., HALT-C trial data presented at the American Association for the Study of Liver Disease meeting, October 2004.

Given the large and growing number of patients who fail current therapy, as well as those who are intolerant to ribavirin or the full dose of pegylated interferon alpha, a serious need exists for improved treatment options for non-responder HCV patients. This need is particularly acute for the largest group of patients, those with genotype 1.

ZADAXIN as a Novel Therapy for Hepatitis C

We are currently evaluating ZADAXIN in combination with pegylated interferon alpha in HCV non-responder patients in two phase 3 trials in the United States. The two trials are multi-center, double-blinded, randomized and placebo-controlled. Both trials have been fully enrolled and we expect that the latest enrolled patients will have completed 48 weeks of treatment and 24 weeks of follow-up observation by the end of 2005. We anticipate that data from both trials will be available by the early part of 2006, and if the data are favorable, we expect to submit an NDA to the FDA by the end of 2006.

If ZADAXIN in combination with pegylated interferon alpha is approved by the FDA, we believe that ZADAXIN could be beneficial in combination with the current standard of care (pegylated interferon alpha with or without ribavirin) as a first line of therapy for all HCV patients, particularly genotype 1 patients who are less likely to respond to current therapy. Additionally, if the data are favorable, our European marketing and development partner Sigma-Tau intends to use these data to file an NDA with the EMEA for regulatory approval in Europe.

Over 500 patients have been enrolled in each trial. The first trial enrolled HCV non-responder patients without cirrhosis of the liver and the second trial enrolled HCV non-responder patients with early cirrhosis. The principle investigators for these trials are Dr. Adrian Di Bisceglie, Chief of Hepatology at the Saint Louis University and Medical Director of the American Liver Foundation, and Dr. Kenneth Sherman, Associate Professor of Medicine and Director of Clinical Trials at the Liver Unit of the University of Cincinnati Medical Center.

Patients in both trials are receiving a 48-week course of therapy of either ZADAXIN (1.6 mg, twice a week) and pegylated interferon alpha (180 mcg, once a week) or placebo and pegylated interferon alpha followed by a 24-week observation period. These treatment and follow-up periods are designed to be consistent with the FDA standard for demonstrating sustained response to HCV therapy. The primary endpoints of each trial are the achievement of SVR measured at week 72 by PCR assay (24 weeks after completing 48 weeks of therapy), and an improvement in the liver histological activity index assessed by liver biopsy at week 72. The secondary endpoints are normalization of ALT (an enzyme that indicates liver damage when present in elevated levels in the liver) measured at week 72, and the end of therapy response rate (ETR) measured at week 48.

Previously published data indicate that ZADAXIN in combination with pegylated interferon alpha has the potential to benefit HCV non-responder patients. In a 12-week dose-ranging study, a group of 31 non-responder patients, all with a high viral load of genotype 1, received 3 different ZADAXIN doses (0.8 mg, 1.6 mg and 3.2 mg, twice a week) in combination with the standard pegylated interferon alpha dose (180 mcg, once a week). The data showed an early virologic response (EVR; defined as a 2 log or greater reduction in HCV RNA measured after 12 weeks of therapy) for patients in each dosing regimen, ranging from 20 to 36 percent across the groups. A patient who demonstrates an EVR may or may not achieve a SVR, and therefore EVR may not be predictive of a successful outcome, especially for a non-responder patient. However, without an EVR, a patient is highly unlikely to achieve an SVR.

ZADAXIN as Part of a Hepatitis C Triple Therapy Combination

Given the need for better HCV therapies, particularly for non-responder patients or those with the difficult-to-treat genotype 1, we are evaluating ZADAXIN's use as part of a triple therapy combination with pegylated interferon alpha and ribavirin. Concurrent with our U.S. phase 3 HCV clinical trials targeting regulatory approval, Sigma-Tau, which has exclusive marketing rights for ZADAXIN in most Western European countries, is conducting a phase 3 triple therapy clinical trial in Europe with a planned enrollment of 550 genotype 1 non-responder patients. Sigma-Tau began enrollment in December 2004 and data from this trial may be available by the end of 2007.

This triple therapy phase 3 clinical trial is multi-center, double-blinded, randomized and placebo-controlled and Sigma-Tau plans to conduct the trial in 40 sites throughout Europe. Professor Mario Rizzetto, Professor of Gastroenterology at the University of Turin in Italy, is the lead investigator for this clinical trial. Patients will be randomized to receive either ZADAXIN (1.6 mg, twice a week) or a placebo (twice a week) and all patients will receive pegylated interferon alpha (180 mcg, once a week) and standard dose of ribavirin (1,000 to 1,200 mg, daily, according to body weight). After completing 48 weeks of treatment, patients will be monitored for a 24-week observation period. The primary endpoint is SVR measured at week 72 at the end of the 24-week observation period. The secondary endpoints are normalization of ALT measured at the end of weeks 48 and 72, absence of HCV RNA measured at week 48, and an improvement in the liver biopsy.

The design of Sigma-Tau's phase 3 triple therapy clinical trial is supported by encouraging results achieved from a small, single-arm triple therapy pilot trial conducted by our licensee in Mexico. Final endpoint results from this 25-patient trial were reported at the annual meeting of the American Association for the Study of Liver Diseases (AASLD) in October 2004 and showed that 19% of genotype 1 non-responder patients achieved an SVR. All of these patients were non-responders to previous therapy of interferon alpha with ribavirin. These data compare favorably to the 9% SVR reported from a separate, unrelated trial that treated genotype 1 non-responder patients with pegylated interferon and a low dose of ribavirin but without ZADAXIN. Although it is difficult to draw conclusions from two separate, unrelated trials, we believe the results achieved from this pilot triple therapy trial are encouraging.

Hepatitis B: Worldwide Market and Current Therapy Options

The World Health Organization estimates that more than 350 million people are chronically infected with the hepatitis B virus worldwide. HBV is most prevalent in sub-Saharan Africa, Asia and the Pacific. We estimate that the worldwide market for hepatitis B therapeutics was approximately $480 million in 2004.

Currently, interferon alpha (both in its standard and pegylated formulations), lamivudine and adefovir dipivoxil are approved for the treatment of HBV. Patients are considered to be successfully cured of HBV if they achieve a sustained seroconversion, a process that is indicated by the disappearance of the marker called hepatitis B e-antigen (HBeAg) and the detection of the antibody to the HBeAg. Interferon alpha is the most effective therapy in eliminating the virus and producing a sustained seroconversion. Lamivudine and adefovir dipivoxil are effective in suppressing the virus, but studies show that prolonged use of lamivudine can cause serious viral mutations that eventually lead to drug resistance. After 5 years of lamivudine therapy, 69% of patients have lamivudine-resistant viral mutations.

ZADAXIN for the Treatment of Hepatitis B

We completed a phase 3 clinical trial in Japan using ZADAXIN as a monotherapy to treat patients chronically infected with HBV. The study showed that 20% of patients treated with ZADAXIN for 6 months achieved a sustained seroconversion and no significant side effects were noted. We are pleased by these results, which will be published in a peer-reviewed, MEDLINE-indexed medical journal in the spring of 2005. In addition, as part of a meta-analysis, earlier ZADAXIN monotherapy HBV studies showed seroconversion rates of 25% to 41%.

These results compare favorably to the data achieved from separate studies using other HBV therapies. Although 12 months of pegylated interferon alpha therapy is successful in inducing a sustained seroconversion in 32% of HBV patients, this therapy also causes severe adverse side-effects for many patients. Lamivudine and adefovir dipivoxil are effective in suppressing the virus but are not considered a cure for most patients. These therapies produce a seroconversion in 16% and 12% of patients, respectively. Additionally, studies show that prolonged use of lamivudine can cause serious viral mutations and eventually lead to drug resistance.

The following chart summarizes sustained seroconversion rates for various therapies, which include the results for ZADAXIN from our Japanese phase 3 clinical trial:

HBV Therapy	Sustained seroconversion
Pegylated interferon alpha (n=271)[1]	32%
ZADAXIN (n=316)[2]	20%
Lamivudine (n=140)[3]	16%
Adefovir dipivoxil (n=171)[4]	12%

[1] Source: Lau, G., AASLD, 2004. Measured after 12 months of therapy and 6 months of follow-up observation.

[2] Source: SciClone Pharmaceuticals, Inc., 2003. Measured after 6 months of therapy and 12 months of follow-up observation. ZADAXIN did not produce any significant side effects or toxicities.

[3] Source: Package insert, Glaxo, 2001. Measured after 12 months of therapy. Long-term use of lamivudine has shown to lead to serious HBV mutations.

[4] Source: Package insert, Gilead Sciences, 2002. Measured after 12 months of therapy.

Despite the favorable data from our phase 3 clinical trial, we may be unable to file a Japanese New Drug Application (JNDA) for ZADAXIN as a therapy for HBV. A JNDA filing requires complete documentation from the phase 1 and phase 2 as well as the phase 3 clinical trials. The phase 1 and phase 2 clinical trials were conducted and sponsored by Schering Plough KK (SPKK), a pharmaceutical company in Japan under a development agreement with SciClone. As we began to prepare the submission necessary for the JNDA, we discovered that we had not received all of the documentation necessary for the submission. After several months of soliciting from SPKK the data and documentation necessary to proceed with the filing in Japan, and after receiving some additional documentation, we have determined that certain information and documentation from earlier stages of the development process has still not been delivered. Furthermore, SciClone is concerned that some of the necessary documentation may not be available at all, and that certain administrative formalities may not have been observed in the drug development process. If the necessary documentation can be obtained or reproduced in the near future, we intend to proceed with the JNDA. We are reviewing our legal rights and remedies with respect to third parties. We continue to seek a resolution of this matter with SPKK.

We cannot assure that a JNDA can be filed, or what the outcome of any legal action by us might be, but we intend to assert our rights vigorously.

Currently, we are enrolling up to 120 patients in a clinical trial in Taiwan using ZADAXIN in combination with lamivudine for the treatment of HBV. Previously reported data from small pilot clinical trials suggest that ZADAXIN combination therapy could increase the response rates for patients taking lamivudine or interferon alone. We expect to report results from this 18-month Taiwanese clinical trial in late 2006.

In 1994, Alpha 1 Biomedicals Inc., from which we acquired certain rights to thymosin alpha 1, completed their 99 patient U.S. phase 3 clinical trial of thymosin alpha 1 as a monotherapy for HBV. After six months of therapy and six months of follow up observation, 25% of patients treated with thymosin alpha 1 achieved the endpoints of the study, negative HBV DNA and loss of the hepatitis B e-antigen, compared to 13% of patients in the placebo control arm. Although nearly twice the number of patients treated with thymosin alpha 1 achieved the endpoints versus the placebo control arm, the small number of patients did not provide enough power to achieve statistical significance. Consequently, Alpha 1 Biomedicals Inc. never submitted these data to the FDA.

Hepatitis Advisory Board

Our Hepatitis Advisory Board provides advice for the research and clinical development of ZADAXIN. The Board includes highly respected thought leaders in the field of hepatology and basic science. As of December 31, 2004, the members of our Hepatitis Advisory Board included the following:

Name	Institution
Jules Dienstag, M.D.	Harvard University, Massachusetts General Hospital
Michael Karin, Ph.D.	University of California, San Diego
Willis Maddrey, M.D.	University of Texas Southwestern Medical Center at Dallas
John McHutchinson, M.D.	Duke University Medical Center
Eugene Schiff, M.D.	University of Miami School of Medicine
Teresa Wright, M.D.	University of California, San Francisco, Veterans Administration Medical Center, GI Center, San Francisco

ZADAXIN as a Therapy for Certain Cancers

In addition to ZADAXIN's potential use for the treatment of infectious diseases, we believe that ZADAXIN's role in activating and directing the body's immune response may also be valuable for the treatment of certain cancers. To that end, there are currently two ongoing trials evaluating ZADAXIN in combination with currently approved therapies for the treatment of malignant melanoma and hepatocellular carcinoma, or liver cancer.

The rate of new cases of malignant melanoma has been steadily increasing since the 1970s. The American Cancer Society estimates that in 2005 there will be 59,580 new cases and about 7,770 estimated deaths from malignant melanoma in the United States alone. If diagnosed early, the cure rate is high for malignant melanoma, however, if the melanoma has spread beyond the skin, the survival time is generally less than five months. Currently interferon alpha and the chemotherapy agent dacarbazine (DTIC) are approved to treat malignant melanoma.

Our partner in Europe, Sigma-Tau, is currently enrolling a targeted 320 stage 4 (metastatic) malignant melanoma patients in a phase 2 clinical trial in over 60 sites throughout Europe. Sigma-Tau estimates that enrollment should be completed by mid-2005.

This trial, funded and conducted by Sigma-Tau, is designed to demonstrate a clinical benefit from using ZADAXIN in combination with standard chemotherapy and low-dose interferon alpha. All patients in this four-arm study are receiving DTIC chemotherapy. In addition to receiving DTIC, each patient is randomly assigned to receive ZADAXIN, interferon alpha, or ZADAXIN (in specific doses, either 1.6 mg or 3.2 mg) plus interferon alpha. Patients are receiving six cycles of therapy for 6 months and will be observed for a period of 12 months after the end of therapy. The endpoints are tumor response and survival. The results of this clinical trial, if positive, are expected to be used in the design of a ZADAXIN combination therapy phase 3 clinical trial for malignant melanoma.

Additionally, we are conducting two phase 2 proof-of-concept trials in the U.S. to evaluate ZADAXIN's effectiveness in the treatment of hepatocellular carcinoma. We intend to gather data from these trials to report by the end of 2005. The first liver cancer pilot trial is evaluating ZADAXIN with chemoembolization, or TACE. The second trial, using radiofrequency ablation, or RFA, with ZADAXIN has enrolled very slowly due to the fact that the type of patient that had previously been considered a potential candidate for RFA, and would therefore qualify for our protocol, is now being placed on the liver transplantation list. At the time this trial began, RFA appeared to be a promising protocol treatment, but this has not proven to be true. Consequently, we will continue the first trial using TACE plus ZADAXIN, and we may incorporate the data from the RFA trial into that of the TACE protocol for final data analysis.

SCV-07

Our other proprietary drug development candidate SCV-07 is currently in the pre-clinical stages of development for the treatment of viral and other infectious diseases. Our objective is to identify a target indication and file an IND application for SCV-07 in the first half of 2005.

SCV-07 is a synthetic dipeptide that has demonstrated immunomodulatory activity by increasing T-cell differentiation and function, biological processes that are necessary for the body to fight off infection. We acquired exclusive worldwide rights, outside of Russia, to SCV-07 from Verta, Ltd., a biotechnology company located in St. Petersburg, Russia.

In September 2002, we reported final results from a phase 2 clinical study conducted by Verta in Russia of SCV-07 in tuberculosis at the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC). After 3 months, 80% (35/44) of tuberculosis patients treated with a five-day regimen of SCV-07 therapy in combination with anti-tuberculosis chemotherapy were no longer contagious, as measured by negative sputum cultures, compared to 37% (10/27) of patients whose treatment did not include SCV-07.

Pegylated ZADAXIN

In May 2004, we entered into a collaborative agreement with Nektar Therapeutics to develop a pegylated formulation of ZADAXIN. Nektar will apply its Advanced PEGylation technology to ZADAXIN with the objective of improving the therapeutic use (less frequent dosing) and potential efficacy (through a higher concentration level in the body for a longer period of time). If the formulation is successful, pegylated ZADAXIN could lead to improved patient compliance due to less frequent dosing and would allow the drug to remain in the body at a higher concentration level for a longer period of time. In addition to potentially enhancing

the use of ZADAXIN in the treatment of hepatitis C and hepatitis B, we believe that a pegylated formulation also could broaden the potential application of ZADAXIN in cancer therapy.

Intellectual Property and Proprietary Rights

Patents

We seek regulatory approval for our products in disease areas with unmet medical need, significant market potential and where we have a proprietary position through patents covering use, process, or composition of matter for our products. For our lead product ZADAXIN, we are the licensee or owner of patents relating to the use of thymosin alpha 1 for certain diseases and its process of manufacture.

We are the exclusive licensee or owner of patents relating to the use of ZADAXIN as a therapy for HCV that do not expire until 2015 in the United States and until 2012 in Japan and the major commercial markets in Europe. In addition, patents relating specifically to the use of thymosin alpha 1 in treating HCV in non-responders to interferon alpha treatment have been issued to us in the United States and various international markets. In the United States, certain European countries and Japan, the period of patent protection may be extended depending on the relevant dates of patent grant and market authorization, and we may, depending on the timing of any future approval, be eligible for such an extension.

We are the exclusive licensee or owners of patents that have been issued in the United States, Japan, China and other international markets relating to the treatment of HBV using thymosin alpha 1. We are the licensee or owner of patents relating to the use of ZADAXIN as a therapy for HBV that do not expire until 2019 in the United States and Europe and 2012 in Japan. We are also the exclusive licensee of patents that have been issued in the United States, a majority of European countries, Japan, and other international markets that relate to the use of thymosin alpha 1 to treat small cell and non-small cell lung cancer. Several corresponding additional patent applications have been issued or patent applications are pending in other countries for each of the above named indications.

For process patents, we are either a patentee or exclusive licensee of use and process patents related to the method of making and therapeutic uses of thymosin alpha 1. Our process patents are directed to methods of making thymosin alpha 1 and have been issued in the United States, a majority of European countries, Japan, Canada, Hong Kong, Taiwan and South Korea. Although the composition of matter patents related to thymosin alpha 1 have expired in the major pharmaceutical markets, we have several composition of matter patents and applications directed to analogues and derivatives of thymosin alpha 1 which have been granted in the United States and in important international markets. Our commercialized product, and the product we are using in our clinical trials, is thymosin alpha 1 and not an analogue or derivative. However, we continue to seek additional proprietary rights relating to the use of thymosin alpha 1. We are the exclusive licensee of an issued U.S. patent relating to the composition of matter of SCV-07 and related compounds, as well as similar pending foreign patent applications.

Proprietary Rights

In addition to our patent protection, we intend to use other means to protect our proprietary rights. We may pursue marketing exclusivity periods that are available under regulatory provisions in certain countries including the United States, Europe and Japan.

Orphan drug protection has been or may be sought where available if such protection also grants additional market exclusivity. We hold an orphan drug product designation for thymosin alpha 1 for hepatocellular carcinoma in the United States and Europe.

We have filed trademark applications worldwide for ZADAXIN and other trademarks that appear on our commercial packaging and promotional literature. Copyrights for the commercial packaging may prevent counterfeit products or genuine but unauthorized products from entering a particular country by parallel importation. We have implemented anti-counterfeiting measures on commercial packaging and we are registering the packaging with customs departments in countries where such procedures exist. We rely upon trade secrets, which we seek to protect in part by entering into confidentiality agreements with our employees, consultants, corporate partners, suppliers and licensees.

Marketing and Sales

We, or our distributors on our behalf, have received approvals from the ministries of health to market and sell ZADAXIN in over 30 countries primarily in Asia, the Middle East and Latin America. ZADAXIN's approvals are principally for the treatment of HBV, with additional approvals in certain countries for the treatment of HCV, as a vaccine adjuvant, or as a chemotherapy adjuvant for

cancer patients with weakened immune systems. We sell ZADAXIN in various international markets through our wholly owned subsidiary, SciClone Pharmaceuticals International Ltd. (SPIL).

China is currently our largest single market for ZADAXIN and accounted for 91%, 88% and 88% of ZADAXIN sales for the years ended December 31, 2004, 2003 and 2002, respectively. China is the world's most populous nation that accounts for approximately one third of the 350 million chronic HBV cases and approximately one fourth of the 170 million chronic HCV cases worldwide. We position ZADAXIN as a high quality, imported, premium priced product and market if for use by hospitals and pharmacies in the major metropolitan areas. SPIL employs approximately 90 medical representatives in China to promote physicians' knowledge and use of ZADAXIN. SPIL is an active participant in regional and international liver disease related medical conferences. To leverage our existing marketing capabilities, we are seeking to expand our product offerings by in-licensing or acquiring the marketing rights to other products that can be effectively and efficiently marketed to physicians by our medical representatives.

In China, the physicians' and their hospital pharmacies' orders for ZADAXIN are fulfilled by licensed ZADAXIN distributors who purchase their supplies from our selected importing agents. SPIL sells ZADAXIN to these well-established, government-licensed importing agents. Our sales are made on a no-return basis, except under limited terms regarding product quality. Sales terms to the importing agents in China typically are for payment in six months to accommodate the importing agents' costs of importation including duties and quality assurance testing fees and the long collection cycle associated with sales within the country. In 2004, China National Pharmaceutical Foreign Trade Corporation, China Meheco Corporation and Guang Dong South Pharaceutical Foreign Trade Co., Ltd accounted for 32%, 29% and 23% of our sales, respectively. No other customer accounted for more than 10% of sales in 2004. In 2003, China National Pharmaceutical Foreign Trade Corporation and China Meheco Corporation accounted for 52% and 14% of sales, respectively. No other customers accounted for more than 10% of sales in 2003. In 2002, China National Pharmaceutical Foreign Trade Corporation and Edward Keller Shanghai Ltd. accounted for 41% and 27% of sales, respectively. No other customers accounted for more than 10% of sales in 2002.

SPIL is registered in the Cayman Islands and has offices in Hong Kong, Beijing, Shanghai, Singapore and Sao Paulo. SPIL orders ZADAXIN from our European manufacturer and contracts with a third party for the storage of our finished goods inventory at warehousing facilities in Hong Kong. SPIL then distributes our product worldwide from these warehousing facilities based on purchase orders from our customers. Under our established distribution arrangements, local importers and distributors are responsible for the importation, inventory, distribution and invoicing of ZADAXIN.

Manufacturing

ZADAXIN is manufactured for us by third parties under exclusive contract manufacturing and supply agreements. We closely monitor production runs of ZADAXIN and regularly conduct our own quality assurance audit programs. We believe the manufacturing facilities of our contract suppliers are in compliance with the FDA's current Good Manufacturing Practices, and the Japanese or European equivalents of such standards.

Contract suppliers in the United States manufacture ZADAXIN for process validation and for our phase 3 clinical trials in the United States. Contract suppliers in Europe manufacture ZADAXIN for our phase 2 and 3 clinical trials in Europe and for sale in other international markets where approved.

In the event of the termination of an agreement with any single supplier, we believe that we would be able to enter into arrangements with other suppliers with similar terms. We do not intend at this time to acquire or establish our own dedicated manufacturing facilities for any of our products. We believe that our current manufacturing partners have enough manufacturing capacity to meet potential market demand should ZADAXIN be approved in the major pharmaceutical markets of the United States, Europe and Japan.

Competition

Our competitors include biopharmaceutical companies, biotechnology firms, universities and other research institutions, both in the United States and abroad, that are actively engaged in research and development or marketing of products in the therapeutic areas we are pursing, particularly HCV, HBV and cancer. Currently, competitors are marketing drugs for HCV, HBV and cancer, or have products in clinical trials. We believe that the principal competitive factors in this industry for a marketed drug include the efficacy, safety, price, therapeutic regimen, manufacturing, quality assurance and associated patents and the capabilities of its marketer.

In addition, most of our competitors, particularly large biopharmaceutical companies, have substantially greater financial, technical, regulatory, manufacturing, marketing and human resource capabilities than SciClone. Most of them also have extensive experience in undertaking the pre-clinical and clinical testing and in obtaining the regulatory approvals necessary to market drugs. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated with our competitors.

For the treatment of HCV, the only products approved by the FDA are interferon alpha, in both standard and pegylated forms, and ribavirin, which is useful only in combination with interferon alpha. There are currently two versions of pegylated interferon alpha being marketed, one by Schering-Plough under the trade name "Peg-Intron," the other by Roche under the trade name "PEGASYS." Schering-Plough markets ribavirin under the trade name "Rebetol" and Roche sells a separate brand of ribavirin under the trade name "COPEGUS."

In the United States, our product ZADAXIN is being evaluated in combination with pegylated interferon alpha for the treatment of HCV patients who have failed to respond to prior therapy with interferon alpha (standard or pegylated) plus ribavirin or with either form of interferon alpha alone. In Europe, ZADAXIN is being evaluated as part of a triple therapy of ZADAXIN, pegylated interferon alpha and ribavirin for the treatment of HCV genotype 1 non-responder patients. Each of the ZADAXIN HCV clinical trials is using the PEGASYS as the pegylated interferon alpha component. We intend to position ZADAXIN as a beneficial addition to current therapy, although we may not be successful.

For the treatment of HBV, current therapies being marketed by competitors include interferon alpha, in both standard and pegylated forms, marketed primarily by Schering-Plough and Roche, nucleoside analogues such as lamivudine, marketed by GlaxoSmithKline, and the nucleotide analogue adefovir, marketed by GlaxoSmithKline and Gilead Sciences. Other potentially competitive products currently under development include Bristol-Myers Squibb's nucleoside analogue, entecavir. In addition to these products, in our largest market China, ZADAXIN faces competition from other synthetic and generic biological extracts, which are locally manufactured and significantly lower priced.

Other companies are researching, developing, or marketing other products for use alone or in combination with standard or pegylated interferon alpha for clinical indications including HCV and HBV. Such competitive products include ribavirin, potentially improved ribavirin molecules and other products not yet in late stage clinical trials such as therapeutic vaccines, protease, polymerase and reverse transcriptase inhibitors. In addition, we expect continuing advancements in and increasing awareness of the use of therapeutics which boost the immune system to fight cancer and infectious diseases. These developments may create new competitors. Future clinical trials may or may not show ZADAXIN to have advantages or clinically significant synergistic value over such existing or future competitive products.

For the treatment of cancer, many companies are researching, developing, or marketing other products for use alone or in combination with other therapies.

Research and Development

A major portion of our operating expenses to date is related to research and development (R&D). R&D expenses consist of independent R&D costs and costs associated with collaborative R&D and in-licensing arrangements. R&D expenses were $17,994,000, $18,949,000 and $11,647,000 for the years ended December 31, 2004, 2003, and 2002, respectively. We intend to maintain our strong commitment to R&D as an essential component of our product development effort. Licensed technology developed by outside parties is an additional source of potential products.

Employees

As of December 31, 2004, we had 143 employees, 29 in the United States and 114 in foreign offices. The increase during 2004 is largely attributable to the hiring of additional medical representatives in China. From time to time, we engage the services of consultants worldwide with pharmaceutical and business backgrounds to assist in our product development and ZADAXIN commercialization activities. We plan to leverage our key personnel by continuing to make extensive use of clinical research organizations, contract laboratories, development consultants and collaborations with pharmaceutical companies to develop and market our products.

Government Regulation

Regulation by governmental authorities in the United States and foreign countries is a significant factor in the manufacturing and marketing of our products, as well as in ongoing research and development activities and in pre-clinical and clinical trials and testing related to our products. When our products are manufactured, tested or sold in the United States, they will be regulated in accordance with the Federal Food, Drug, and Cosmetic Act, commonly referred to as the FD&C Act and the U.S. Public Health Service Act. In addition to obtaining FDA approval for each product, each manufacturing establishment must be registered with the FDA. Manufacturing establishments are subject to inspections by the FDA and by other federal, state and local agencies and must comply with current U.S. Good Manufacturing Practices (cGMP). In complying with cGMP standards, manufacturers must continue to expend time, money and effort in the area of production and quality assurance to ensure full technical compliance.

The steps required before a new drug or biological product may be distributed commercially in the United States generally include:

- conducting appropriate pre-clinical laboratory evaluations, including animal studies, in compliance with the FDA's Good Laboratory Practice (GLP) requirements, to assess the potential safety and efficacy of the product, and to characterize and document the product's chemistry, manufacturing controls, formulation and stability;

- submitting the results of these evaluations and tests to the FDA, along with manufacturing information and analytical data, in an IND, and receiving approval from the FDA that the studies proposed under the IND are allowed to proceed;

- obtaining approval of Institutional Review Boards (IRBs) to introduce the drug into humans in clinical studies;

- conducting adequate and well-controlled human clinical trials in compliance with the FDA's Good Clinical Practice (GCP) requirements that establish the safety and efficacy of the drug product candidate for the intended use, typically in the following three sequential, or slightly overlapping stages:

  - *Phase 1:* The drug is initially introduced into healthy human subjects or patients and tested for safety, dose tolerance, absorption, metabolism, distribution and excretion;

  - *Phase 2:* The drug is studied in patients to identify possible adverse effects and safety risks, to determine dose tolerance and the optimal dosage and to collect initial efficacy data;

  - *Phase 3:* The drug is studied in an expanded patient population at multiple clinical study sites, to confirm efficacy and safety at the optimized dose, by measuring a primary endpoint established at the outset of the study, and comparing it to that of established therapies, if any; and when required;

  - *Phase 4:* The drug is studied in an expanded patient population in a post-approval setting for continued monitoring of safety and sometimes continued efficacy;

- submitting to the FDA the results of pre-clinical studies, clinical studies, and adequate data on chemistry, manufacturing and control information to ensure reproducible product quality batch after batch, in an NDA or Biologics License Application (BLA); and

- obtaining FDA approval of the NDA or BLA, including inspection and approval of the product manufacturing facility as compliant with cGMP requirements, prior to any commercial sale or shipment of the pharmaceutical agent.

When used in connection with trials and filings in other countries, terms such as "phase 1," "phase 2," "phase 3," "phase 4," "new drug application" and "marketing application" refer to what we believe are comparable trials and filings in these other countries.

The process of obtaining regulatory approval is lengthy, uncertain, and requires the expenditure of substantial resources. Each NDA or BLA must be accompanied by a user fee, pursuant to the requirements of the Prescription Drug User Fee Act, or PDUFA, and its amendments. According to the FDA’s fee schedule, effective through September 30, 2005, the user fee for an application requiring clinical data, such as an NDA or BLA, is $672,000. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual product fee for prescription drugs and biologics ($41,710 for the fiscal year 2005), and an annual establishment fee ($262,000) on facilities used to manufacture prescription drugs and biologics. Fee waivers or reductions are available in certain

circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the drug also includes a non-orphan indication, and if a contract manufacturer is used, the contract manufacturer is responsible for the establishment fee.

After FDA approval has been obtained, the FDA will require post-marketing reporting to monitor the side effects of the drug. Further studies may be required to provide additional data on the product's risks, benefits, and optimal use, and will be required to gain approval for the use of the product as a treatment for clinical indications other than those for which the product was initially tested. Results of post-marketing programs may limit or expand the further marketing of the product. Further, if there are any modifications to the drug, including changes in indication, labeling, or a change in the manufacturing process or manufacturing facility, an NDA or BLA supplement may be required to be submitted to the FDA.

Additionally, after the FDA has authorized a drug product to enter commercial distribution, numerous regulatory requirements apply. These include, among others, the cGMPs, which require manufacturers to follow extensive design, testing, control, documentation and other quality assurance procedures during the manufacturing process; labeling regulations; the FDA's general prohibition against promoting drug products for unapproved or "off-label" uses; and adverse event reporting regulations, which require that manufacturers report to the FDA if their drug may have caused or contributed to a death or serious injury. The FDA has broad post-market and regulatory and enforcement powers. Failure to comply with the applicable U.S. drug regulatory requirements could result in, among other things, warning letters, fines, injunctions, consent decrees, civil penalties, refunds, recalls or seizures of products (which would result in the cessation or reduction of production volume), total or partial suspension of production, withdrawals or suspensions of current product applications, and criminal prosecution. Adverse events related to a drug product in any existing or future markets could cause regulatory authorities to withdraw market approval for such product.

The FD&C Act includes provisions intended to facilitate and expedite the development and review of drugs and biological products intended for treatment of serious or life-threatening conditions that demonstrate the potential to address unmet medical needs for such conditions. These provisions set forth a procedure for designation of a drug as a "fast track product." Concurrent with or after an IND is filed, the sponsor may request designation as a fast track product, and the FDA is required to respond within 60 days.

An advantage of fast track designation is that sponsors may submit, and the FDA may commence review of, portions of an application before the complete application is submitted, provided that the FDA approves a schedule for submission of the completed application. The sponsor of a fast track product also may seek and obtain FDA approval based upon a determination that the product has an effect on a clinical endpoint or on a surrogate endpoint that is reasonably likely to predict clinical benefit. A product approved on this basis is subject to rigorous postmarket compliance requirements, and the sponsor may be required to conduct post-approval studies to validate and/or confirm the endpoint. The FDA may withdraw approval of a fast track product if, for example, the sponsor fails to conduct required post-approval studies or disseminates false or misleading promotional materials.

The Orphan Drug provisions of the FD&C Act provide incentives to drug and biologics suppliers to develop and supply drugs for the treatment of rare diseases, currently defined as diseases that affect fewer than 200,000 individuals in the United States or, for a disease that affects more than 200,000 individuals in the United States, where the sponsor does not realistically anticipate its product becoming profitable. Under these provisions, a supplier of a designated orphan product can seek tax benefits, and the holder of the first FDA approval of a designated orphan product will be granted a seven year period of marketing exclusivity for that product for the orphan indication. The marketing exclusivity of an orphan drug would prevent other sponsors from obtaining approval of the same drug for the same indication without a showing of clinical superiority. It would not prevent other types of drugs from being approved for the same use. We have been granted orphan designation by the FDA for ZADAXIN for treatment of hepatocellular carcinoma.

In the European Union, incentives for suppliers to develop medicinal products for the treatment of rare diseases are provided pursuant to the Orphan Medicinal Products Regulation (Regulation (EC) 141/2000). Orphan medicinal products are those products designed to diagnose, treat or prevent a condition which occurs so infrequently that the cost of developing and bringing the product to the market would not be recovered by the expected sale of the product. In the EU, the criterion for designation is a prevalence of the relevant condition in no more than 5 per 10,000 of the population. The incentives include, amongst others, a reduction in the fees payable in respect of the marketing authorization application, protocol assistance for clinical trials in support of the application, and marketing exclusivity once the authorization is granted. In the EU, marketing exclusivity is granted to products with an orphan drug designation for a period of 10 years during which the EU will not accept another application for a marketing authorization for the same therapeutic indication in respect of a similar medicinal product, unless the second applicant can show its product is safer, more effective or otherwise clinically superior. A similar medicinal product is defined as a medicinal product containing a similar active substance as contained in the authorized orphan medicinal product.

We have been granted orphan designation throughout the EU for ZADAXIN for treatment of hepatocellular carcinoma, and for CPX for the treatment of cystic fibrosis. However, it should be noted that, as in the United States, the granting of orphan drug status in the EU does not affect the likelihood of success of obtaining regulatory approval or marketing authorization for the relevant product in any way.

Under the Drug Price Competition and Patent Term Restoration Act of 1984, or DPCPTRA, a sponsor may be granted marketing exclusivity for a period of time following FDA approval of certain drug applications, regardless of patent status, if the drug is a new chemical entity or new clinical studies were used to support the marketing application. This marketing exclusivity would prevent a third party from obtaining FDA approval for a similar or identical drug through an Abbreviated New Drug Application, or ANDA, which is the application form typically used by suppliers seeking approval of a generic drug, or 505(b)(2) application. The DPCPTRA also allows a patent owner to extend the term of the patent for a period equal to one-half the period of time elapsed between the filing of an IND and the filing of the corresponding NDA plus the period of time between the filing of the NDA and FDA approval with the maximum patent extension term being five years. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for the patent term extension.

The Best Pharmaceuticals for Children Act provides an additional six months of marketing exclusivity for new or marketed drugs for certain pediatric testing conducted at the written request of the FDA. The Pediatric Research Equity Act authorizes FDA to require pediatric studies for drugs and biological products to ensure the drugs' or products' safety and effectiveness in children. This Act required that new NDAs, BLAs or supplements to NDAs or BLAs contain data assessing the safety and effectiveness for the claimed indication in all relevant pediatric subpopulations. Dosing and administration must be supported for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant deferrals for submission of data, or full or partial waivers.

We may seek the benefits of additional orphan, exclusivity, patent term extension, or fast track provisions, with respect to ZADAXIN but we cannot assure that we will be able to obtain any such benefits.

We are subject to foreign regulations governing human clinical trials and pharmaceutical sales. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries is required prior to the commencement of marketing of our products in those countries. The approval process varies from country to country and the time required for approval may be longer or shorter than that required for FDA approval. In general, foreign countries use one of three forms of regulatory approval process. In one form, local clinical trials must be undertaken and the data must be compiled and submitted for review and approval. In Japan, for example, the process is time consuming and costly because certain pre-clinical studies and clinical trials must be conducted in Japan. A second form of approval process requires clinical trial submissions, but permits use of foreign clinical trials and typically also requires some form of local trial as well. A third form of approval process does not require local clinical trials, but rather contemplates submission of an application including proof of approval by countries that have clinical trial review procedures. Thus, a prior approval in one or more of the United States, Japan, most European Union countries or Australia, among others, is often sufficient for approval in countries using this third form of approval process.

The FDA regulates the export of drugs or bulk pharmaceuticals from the United States. In general, a drug that has been approved for commercial sale in the United States may be exported for commercial sale. An unapproved drug may be exported to a "listed country" (Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, and countries in the European Union and the European Economic Area) for investigational purposes without FDA authorization if exported in accordance with laws of the foreign country, and in accordance with the export requirements. Export of drugs to an unlisted country for clinical trial purposes continues to require FDA approval. An unapproved drug can be exported to any country for commercial purposes without prior FDA approval, provided that the drug (i) complies with the laws of that country, and (ii) has valid marketing authorization or the equivalent from the appropriate authority in a listed country. Export of drugs not approved in the United States that do not have marketing authorization in a listed country continue to require FDA export approval. We have obtained, where necessary, FDA approval for all exports of ZADAXIN from the United States for clinical trial purposes, and will seek to obtain FDA approval, where necessary, for any future shipments from the United States to any unlisted country.

We are also subject to various federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with research work and preclinical and clinical trials and testing. The extent of government regulation that might result from future legislation or administrative action in these areas cannot be accurately predicted and could prevent or delay regulatory approval of any of our products.

The level of revenues and profitability of pharmaceutical companies may be affected by the continuing efforts of governmental and third party payors to contain or reduce the costs of health care through various means, including the extent and availability of reimbursement. We are unable to predict when any proposed health care reforms will be implemented, if ever, or the effect of the implemented reforms on our business. Our ability to commercialize future products will depend in part on the extent to which coverage and reimbursement for the products will be available from government and health administration authorities, private health insurers, and other third-party payors.

Third-Party Reimbursement

Our ability to successfully commercialize our products may depend in part on the extent to which coverage and reimbursement to patients for our products will be available from government health care programs, private health insurers and other third-party payors or organizations. Significant uncertainty exists as to the reimbursement status of new therapeutic products, such as ZADAXIN. In most of the markets in which we are currently approved to sell ZADAXIN, reimbursement for ZADAXIN under government or private health insurance programs is not yet widely available, and in many of these countries government resources and per capita income may be so low that our products will be prohibitively expensive. In the United States, Europe and Japan, proposed health care reforms could limit the amount of governmental or third-party reimbursement available for our products should they be approved for sale in these markets. Various governments and third-party payors are trying to contain or reduce the costs of health care through various means. We expect that there will continue to be legislative efforts and proposals to implement such government controls.

Available Information

We file electronically with the Securities and Exchange Commission (or SEC) our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. The public may read or copy any materials we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that site is http://www.sec.gov.

You may obtain a free copy of our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act (15 U.S.C. 78m(a) or 78o(d)) on the day of filing with the SEC on our website on the World Wide Web at http:///www.sciclone.com, by contacting the Investor Relations Department at our corporate offices by calling 800-724-2566 or by sending an e-mail message to investorrelations@sciclone.com.

Executive Officers of the Registrant

As of March 9, 2005, the executive officers of the Company, who are elected by and serve at the discretion of the Board of Directors, were as follows:

Name	Age	Position
Alfred R. Rudolph, M.D	57	Chief Operating Officer
Richard A. Waldron	51	Chief Financial Officer and Secretary
Hans P. Schmid	53	Managing Director, SciClone Pharmaceuticals International Ltd.

Alfred R. Rudolph, M.D. has served as our Chief Operating Officer since 1998. In July 2004, Dr. Rudolph and Mr. Waldron were appointed jointly to the Office of the President. Dr. Rudolph has over 30 years of experience in the biopharmaceutical industry. Since joining us in April 1997, Dr. Rudolph has been responsible for the clinical, research, regulatory, manufacturing, and quality assurance functions of our Company. Before joining us, Dr. Rudolph was President and Chief Operating Officer of Neptune Pharmaceuticals, Inc., a marine-based natural product screening company. Previously, Dr. Rudolph was Senior Vice President of T Cell Sciences, Inc., Director of Clinical Operations at Cetus Corporation, and Clinical Assistant Professor of Medicine at University of California, San Francisco. He began his pharmaceutical career with Bristol Myers, where he worked in cancer drug development. Dr. Rudolph earned a B.S. in Electrical Engineering from the University of Rochester, and completed his medical training in Hemotology-Oncology at Syracuse University.

Richard A. Waldron has served as our Chief Financial Officer since 2001. In July 2004, Mr. Waldron and Dr. Rudolph were appointed jointly to the Office of the President. Mr. Waldron has over 20 years of experience in the finance and management of biotechnology companies. Prior to joining us in March 2001, he was Vice President and Chief Financial Officer from June 1999 to August 2000 for Genelabs Technologies, Inc. and from July 1995 through March 1999, he was Vice President and Chief Financial Officer of GeneMedicine, Inc. From 1990 to 1995, he was a managing director and the head of finance for technology-based companies at Rauscher Pierce Refsnes, Inc., an investment banking firm. From 1985 to 1990, he was a senior vice president responsible for health care investment banking at Cowen & Company. Mr. Waldron received his M.B.A. degree with honors from Harvard University and his A.B. degree magna cum laude in Economics from Princeton University.

Hans P. Schmid has served as Managing Director for SciClone Pharmaceuticals International Ltd. since July 2004. He previously served as Vice President, Finance, Administration and Business Development since joining SciClone in May 2001. He has over 25 years of financial and pharmaceutical experience in the U.S. and international markets. Prior to joining SciClone, Mr. Schmid was Chief Financial Officer from December 1999 to April 2001 for Questcor Pharmaceuticals, Inc. and Senior Vice President, International Business Development from February 1997 to September 1999 for Oread, Inc., a contract pharmaceutical company. From 1985 to 1997 he worked at Syntex Corporation as Vice President of Finance and Administration for Pharmaceutical Operations Asia/Pacific region and at F. Hoffmann-LaRoche as Senior Vice President, Finance and Head of Administrative Services for Roche Bioscience. Previously he held financial and operational positions with Itel Corporation in Germany, Japan, England and the United States. He received his B.A. degree from the Commercial Trade School, Lucerne, Switzerland, and has studied International Business Management and Finance at San Francisco State University.

There are no family relationships among any of the directors or executive officers of the Company.

Item 2. ***Properties***

We currently lease approximately 22,000 square feet of office space at our headquarters in San Mateo, California and limited office space in Beijing, Hong Kong, Shanghai, Singapore, Tokyo and Sao Paulo. We believe that our existing facilities will be adequate for our current needs and that additional space will be available as needed.

Item 3. ***Legal Proceedings***

None

Item 4. ***Submission of Matters to a Vote of Security Holders***

No matter was submitted to a vote of security holders during the fourth quarter of the fiscal year ended December 31, 2004.

PART II

Item 5. ***Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchase of Equity Securities***

Our Common Stock trades on The NASDAQ National Market under the symbol "SCLN."

The following table sets forth the high and low sale prices per share for the quarterly periods indicated, as reported by The NASDAQ National Market. The quotations shown represent inter-dealer prices without adjustment for retail markups, markdowns, or commissions, and may not necessarily reflect actual transactions.

	Price Range Common Stock	
	High	Low
2004		
4th quarter	$ 4.86	$ 3.54
3rd quarter	5.17	3.30
2nd quarter	5.88	4.40
1st quarter	8.19	5.06
2003		
4th quarter	$ 9.01	$ 6.41
3rd quarter	9.76	6.36
2nd quarter	9.10	5.15
1st quarter	6.12	3.10

Stockholders

As of March 9, 2005, there were approximately 400 holders of record of our common stock and 44,696,701 shares of common stock issued and outstanding.

Dividends

We have not paid any dividends on our common stock during the fiscal years ended December 31, 2004, 2003, and 2002 and currently intend to retain any future earnings for use in our business.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by Item 201(d) of Regulation S-K is incorporated by reference from the section entitled "Equity Compensation Plan Information" in Part III, Item 12 of this Form 10-K.

Item 6. ***Selected Consolidated Financial Data***

This section presents selected historical financial data for each of the last five fiscal years and is qualified by reference to and should be read in conjunction with the consolidated financial statements and notes thereto included elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,				
	2004	2003	2002	2001	2000
Statement of Operations data:					
Product sales	$ 22,765,000	$ 31,732,000	$ 17,101,000	$ 13,831,000	$ 15,357,000
Contract revenue	1,631,000	806,000	671,000	—	—
Total revenues	24,396,000	32,538,000	17,772,000	13,831,000	15,357,000
Cost of product sales	4,577,000	5,636,000	3,487,000	2,742,000	3,113,000
Gross margin	19,819,000	26,902,000	14,285,000	11,089,000	12,244,000
Operating expenses:					
Research and development	17,994,000	18,949,000	11,647,000	8,561,000	4,182,000
Sales and marketing	9,665,000	9,018,000	8,724,000	8,764,000	7,720,000
General and administrative	6,311,000	4,134,000	3,902,000	3,897,000	3,538,000
Total operating expenses	33,970,000	32,101,000	24,273,000	21,222,000	15,440,000
Loss from operations	(14,151,000)	(5,199,000)	(9,988,000)	(10,133,000)	(3,196,000)
Income from payment on note receivable from former officer	—	—	—	3,497,000	400,000
Interest and investment income[(1)]	1,285,000	266,000	323,000	751,000	1,066,000
Interest expense	(361,000)	(361,000)	(361,000)	(334,000)	(36,000)
Other income (expense), net	(51,000)	19,000	(11,000)	(13,000)	49,000
Net loss	$ (13,278,000)	$ (5,275,000)	$ (10,037,000)	$ (6,232,000)	$ (1,717,000)
Basic and diluted net loss per share	$ (0.30)	$ (0.13)	$ (0.29)	$ (0.19)	$ (0.06)
Weighted average shares used in computing basic and diluted net loss per share	44,626,337	39,568,199	35,002,003	32,356,287	29,904,924

[(1)] For the year ended December 31, 2004, interest and investment income included an approximate gain of $697,000 from sale of equity securities.

	December 31,				
	2004	2003	2002	2001	2000
Balance Sheet data:					
Cash, cash equivalents and investments	$ 51,299,000	$ 62,975,000	$ 21,150,000	$ 16,468,000	$ 22,497,000
Working capital	55,427,000	72,950,000	29,116,000	26,930,000	30,281,000
Total assets	69,709,000	83,822,000	37,111,000	32,096,000	36,167,000
Other long-term liabilities	1,044,000	900,000	—	—	—
Total stockholders' equity	55,123,000	68,250,000	23,354,000	22,774,000	28,077,000
Convertible notes payable	5,600,000	5,600,000	5,600,000	5,600,000	4,000,000

Item 7. ***Management's Discussion and Analysis of Financial Condition and Results of Operations***

This Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the "Selected Consolidated Financial Data" and our consolidated financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K. This Management's Discussion and Analysis of Financial Condition and Results of Operations and other parts of this Annual Report on Form 10-K contain forward-looking statements which involve risks and uncertainties. See "Note Regarding Forward-Looking Statements" and "Risk Factors" contained in this Annual Report on Form 10-K.

Overview

Our current primary business objective is to obtain regulatory approval for and commercialize ZADAXIN as part of combination therapy for the treatment of HCV in the United States and in Europe. Our long term business objective is to be a leading biopharmaceutical company engaged in the development and commercialization of therapeutics to treat life-threatening diseases.

During the periods encompassed by this Annual Report on Form 10-K, we have devoted substantially all of our resources to our ZADAXIN clinical trials and our ZADAXIN commercialization activities. Our primary focus has been the clinical development of ZADAXIN as a part of a new combination therapy for the treatment of hepatitis C. We believe that the worldwide market for HCV therapies was approximately $3 billion in 2004 and could exceed $8 billion in 2012 and that the United States, Europe and Japan account for essentially all of this market opportunity. Currently, there are only two approved and marketed therapies for hepatitis C, interferon alpha (predominantly in pegylated forms) and ribavirin in combination with interferon alpha. Two large pharmaceutical companies, Schering-Plough and Roche, each market their brands of pegylated interferon alpha and ribavirin and dominate the hepatitis C therapeutic market. Our strategy is to develop ZADAXIN to be used in combination with and to improve the efficacy of current therapy, and we are currently conducting in the United States two phase 3 hepatitis C clinical trials of ZADAXIN in combination with pegylated interferon alpha. We intend to complete these trials by the end of 2005 and, if the results are successful, file a NDA by the end of 2006.

We estimate the worldwide market for HBV therapeutics was approximately $480 million in 2004 and it is expected to increase to over $2 billion in 2012. The largest market for hepatitis B therapies is Asia where we have regulatory approval in several countries. Our commercialization and marketing activities to date have been concentrated on China.

We manufacture ZADAXIN for sale, and for our clinical trials, through third party contract manufacturers, and we conduct our research and development efforts principally through arrangements with clinical research sites, contract research organizations and universities.

From commencement of operations through December 31, 2004, we have an accumulated deficit of approximately $152,000,000. At least over the next few years, we expect net losses to increase due to increased operating expenses as we expand our research and development, clinical testing and sales and marketing capabilities. Our ability to achieve and sustain operating profitability is primarily dependent on the execution and successful completion of ZADAXIN clinical trials and securing regulatory approvals for ZADAXIN in the major pharmaceutical markets of the United States, Europe, and Japan, and, if approved in those countries, the successful commercialization and marketing of ZADAXIN. In addition, other factors may also impact our ability to achieve and sustain operating profitability, including the pricing of ZADAXIN and its manufacturing and marketing costs, our ability to compete in pharmaceutical markets, the cost of long-term product development and commercialization programs, the timing and costs of acquiring rights to additional drugs, our ability to fund our operations and the entrance into and extension of agreements for product development and commercialization, where appropriate.

We expect quarterly net sales for 2005 to be slightly higher to those reported in 2004. Expected research and development expenses for 2005 are higher than research and development expenses for 2004 due to increased expenses for the phase 3 hepatitis C clinical trial in Europe as well as for the development of SCV-07. Expected net loss and net loss per share for 2005 are higher than net loss and net loss per share for 2004 based on higher research and development expenses and general and administrative expenses. Cash, cash equivalents and short-term investments at December 31, 2005 are expected to be lower than at December 31, 2004 primarily due to the expected net loss from operations and the assumption that the $4 million convertible note due in December 2005 will be repaid rather than converted.

Our operating results may fluctuate from quarter to quarter and these fluctuations may be substantial as a result of, among other factors, the number, timing, costs and results of preclinical and clinical trials of our products, market acceptance of ZADAXIN and the timing of orders for ZADAXIN from international markets, particularly China, the regulatory approval process, the timing of FDA or

international regulatory approvals, and the acquisition of additional product rights and the funding, if any, provided as a result of corporate partnering arrangements.

Critical Accounting Policies

General

We have identified the policies below as critical to our business operations and the understanding of our results of operations. The impact and any associated risks related to these policies on our business operations is discussed throughout "Management's Discussion and Analysis of Financial Condition and Results of Operations" where such policies affect our reported and expected financial results. For a detailed discussion on the application of these and other accounting policies, see Note 1 in the "Notes to our Consolidated Financial Statements" in Part II, Item 8 of this Annual Report on Form 10-K. The Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United Sates, which requires us to make estimates and assumptions that affect the reported amount of assets and liabilities, disclosure of contingent assets and liabilities at the date of our financial statements, and the reported amounts of revenue and expenses during the reporting period. On an on-going basis, we evaluate the relevance of our estimates. We base our estimates on historical experience and on various other market specific assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. There can be no assurance that actual results will not differ from those estimates.

Revenue Recognition

We recognize revenue from product sales at the time of shipment. There are no significant customer acceptance requirements or post-shipment obligations on our part. Sales to importing agents or distributors are recognized at time of shipment when title to the product is transferred to them, and they do not have contractual rights of return except under limited terms regarding product quality. However, we will replace products that have expired or are deemed to be damaged or defective when delivered. We exercise judgment in estimating return reserves. Payments by the importing agents and distributors are not contingent upon sale to the end user by the importing agents or distributors.

Contract revenue for research and development is recorded as earned based on the performance requirements of the contract. Nonrefundable contract fees for which no further performance obligations exist, and for which there is no continuing involvement by us, are recognized on the earlier of when the payments are received or when collection is assured. We exercise judgment in determining the period over which our performance obligations have been fulfilled which can have an impact on the timing and amount of revenue that is recognized in a particular reporting period.

Revenue associated with substantive performance milestones is recognized based on the achievement of the milestones, as defined in the respective agreements and provided that (i) the milestone event is substantive and its achievement is not reasonably assured at the inception of the agreement and (ii) there are no future performance obligations associated with the milestone payment. We exercise judgment in our determination of the achievement of milestones which can have an impact on the timing and amount of revenue recognized in a particular reporting period.

Amounts invoiced relating to arrangements where revenue cannot be recognized are reflected on our balance sheet as deferred revenue and recognized as the applicable revenue recognition criteria are satisfied.

Accounts Receivable

We are required to estimate the collectibility of our trade receivables. We maintain reserves for credit losses, and such losses have been within our expectations. We recognize reserves for bad debts ranging from 25% to 100% of past due accounts receivable based on the length of time the receivables are past due and our collectibility experience. A considerable amount of judgment is required in assessing the ultimate realization of these receivables including, but not limited to, an analysis of the historical payment patterns of our customers, individual customer circumstances and their geographic region including a review of the local economic environment. Our ability to collect outstanding receivables from our customers is critical to our operating performance and cash flows. We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. If the financial condition of our customers or the economic environment in which they operate were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required which would increase our general and

administrative expenses and increase our reported net loss. Conversely, if actual credit losses are significantly less than our reserve, this would decrease our general and administrative expenses and decrease our reported net loss.

Inventories

Our inventories are stated at the lower of cost or realizable market value. In assessing the ultimate realization of inventories, we are required to make judgments as to future demand requirements and compare that with the current inventory levels. We have begun production with a new contract manufacturer and are currently in the process of qualifying the product to permit its importation into China. Our inventory levels decreased during the second half of 2004. We expect to begin to build inventory levels in the second quarter of 2005 to ensure an uninterrupted supply of product for our customers in China. If we are unable to qualify in a timely fashion the product produced by the new contract manufacturer, we may determine that some of this inventory may not be saleable and could result in writedowns of inventory and in a net loss.

Impairment of Intangible Assets

At December 31, 2004, we had net intangible assets of $542,000 related to ZADAXIN product rights and had never recorded any impairment losses related to intangible assets. In assessing the recoverability of our intangible assets we must make assumptions regarding estimated future cash flows and other factors to determine the fair value of the respective assets. If these estimates or their related assumptions change in the future, we may be required to record impairment charges for these assets.

Research and Development Expenses

Our research and development expenses are principally incurred for our phase 3 clinical trials in the United States. Research and development expenses are charged to operations as incurred. Our cost accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous institutions that conduct the clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients, and the completion of portions of the clinical trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. Expenses related to grants to the institutions are accrued based on the level of patient enrollment and activity according to the protocol. In general, these expenses will be higher for the initial and final months of a patient's scheduled 18 months of treatment and observation. Expenses relating to the clinical research organizations or other entities managing the trials and laboratory and other direct expenses are recognized in the period they are estimated to be incurred and the services performed. We monitor active patient enrollment levels and related activity to the extent possible and adjust our estimates accordingly; however, if management has underestimated activity levels associated with various studies at a given point in time, we could underestimate our actual research and development expenses, requiring the recording of additional expenses and an increase in net loss.

Stock Option Valuation

The preparation of the financial statement footnotes requires us to estimate the fair value of stock options granted to employees and directors. While fair value may be readily determinable for awards of stock, market quotes are not available for long-term, nontransferable stock options because these instruments are not traded. We currently use the Black-Scholes option pricing model to estimate the fair value of employee stock options. Option valuation models require the input of highly subjective assumptions, including stock price volatility. Changes to the subjective input assumptions could materially affect the estimated fair value of our stock options. We are currently evaluating our option valuation methodologies and assumptions in light of a new accounting standard related to employee stock options.

Results of Operations

Product sales were $22,765,000, $31,732,000, and $17,101,000 for the years ended December 31, 2004, 2003 and 2002, respectively, and all were derived from sales of ZADAXIN. Sales to customers in China accounted for approximately 91%, 88% and 88% of this revenue for the years ended December 31, 2004, 2003 and 2002, respectively. Product prices have remained stable throughout the 2002, 2003 and 2004 periods. Of the total increase in sales of $14,631,000 from 2002 to 2003, approximately $11,000,000 was from an unanticipated temporary increase in demand for ZADAXIN from hospitals in China at the time of the SARS outbreak during the second quarter of 2003.

For the years ended December 31, 2004, 2003 and 2002, sales to between four and six importing agents in China accounted for approximately 91%, 88% and 88%, respectively of our product sales. The single largest customer accounting for 32%, 52% and 41% of sales for the years ended December 31, 2004, 2003 and 2002, respectively was the same importing agent. As of December 31, 2004, approximately $9,609,000 or, 90% of our accounts receivable were attributable to four customers in China. We perform on-going credit evaluations of our customers' financial condition, and generally do not require collateral from our customers.

Contract revenue was $1,631,000, $806,000, and $671,000 for the years ended December 31, 2004, 2003 and 2002, respectively. The contract revenue includes a $1,000,000 payment we received from Sigma-Tau in June 2004 relating to the completion of enrollment of our U.S. phase 3 HCV clinical trials. The remaining contract revenue recognized in 2002, 2003 and 2004 is in connection with the $2,685,000 payment we received from Sigma-Tau in January 2002. This revenue is recognized as contract revenue over the course of the ZADAXIN U.S. phase 3 HCV clinical trials and the period of sharing the clinical data from with Sigma-Tau in accordance with the requirements under our contract.

Gross margin was 81%, 83% and 82% in 2004, 2003 and 2002, respectively. The increase in gross margin in 2003 was largely attributable to product-related fixed costs being spread over the significantly larger volume of units sold. We expect cost of product sales and hence gross margin to vary from year to year, depending upon the level of ZADAXIN sales, the absorption of product-related fixed costs, and any charges associated with excess or expiring finished product inventory.

Research and development (R&D) expenses were $17,994,000, $18,949,000 and $11,647,000 for the years ended December 31, 2004, 2003, and 2002, respectively. The decrease in 2004 was primarily related to the U.S. phase 3 hepatitis C clinical trials nearing completion by the end of 2005. The increase in 2003 was primarily to support our ZADAXIN phase 3 HCV clinical trials, in the United States. In 2004, 2003 and 2002, R&D expenses represented approximately 53%, 59% and 48%, respectively, of our total costs and expenses. The major components of R&D expenses consist of clinical studies performed by clinical trial institutions and contract research organizations, related materials and supplies, preclinical work, pharmaceutical development, personnel costs, including salaries and benefits, third party research funding, and overhead allocations consisting of various support and facilities related costs. Our research and development activities are also separated into three main categories: research, clinical development and pharmaceutical development. Research costs typically consist of preclinical and toxicology work. Clinical development costs essentially include clinical trials. Pharmaceutical development costs consist of product formulation and chemical analysis. During 2004, we recorded approximately $4,100,000 on research, $11,800,000 on clinical development, and $2,100,000 on pharmaceutical development activities. This compares to expenses in 2003 of approximately $2,100,000 on research, $14,500,000 on clinical development, and $2,300,000 on pharmaceutical development activities and expenses in 2002 of approximately $2,300,000 on research, $8,300,000 on clinical development, and $1,100,000 on pharmaceutical development activities.

The initiation and continuation of our current clinical development programs has had and will continue to have a significant effect on our research and development expenses. In general, we expect research and development expenses to increase at least over the next few years and to vary substantially from quarter to quarter as we pursue our strategy of initiating additional preclinical and clinical trials and testing, acquiring product rights, and expanding regulatory activities. An expansion or significant extension of our clinical development programs may require us to seek additional capital resources.

Sales and marketing expenses were $9,665,000, $9,018,000 and $8,724,000 for the years ended December 31, 2004, 2003 and 2002, respectively. The year-to-year increases from 2002 to 2004 were related to increased payroll expenses and expenses for advertising and conferences associated with the expansion of our marketing efforts for ZADAXIN. We expect sales and marketing expenses for 2005 to be similar to those incurred in 2004.

General and administrative expenses were $6,311,000, $4,134,000 and $3,902,000 for the years ended December 31, 2004, 2003 and 2002, respectively. The year-to-year increases from 2002 to 2004 were attributable to greater general and administrative activities to support an increased level of research and development on our late-stage clinical programs. In addition, the increase in the 2004 period was attributable to a non-recurring expense incurred in connection with the separation of our former Chief Executive Officer from the Company in July 2004 and to greater general and administrative activities associated with increased securities regulation requirements. In the near term, we expect increased general and administrative expenses as we increase our general and administrative activities to support increased expenditures on business development, legal and regulatory activities.

Interest and investment income was approximately $1,285,000, $266,000 and $323,000 for the years ended December 31, 2004, 2003 and 2002, respectively. The increase from 2003 to 2004 was primarily related to a gain from the sale of equity securities in the amount of approximately $697,000 and the remaining increase was due to higher cash balances earning interest in the 2004 period.

Interest expense relating to $5,600,000 of convertible notes payable was $361,000 for each of the years ended December 31, 2004, 2003 and 2002.

Net loss for the years ended December 31, 2004, 2003 and 2002 was $13,278,000, $5,275,000 and $10,037,000, respectively. Net loss was higher in 2004 than in 2003 principally due to higher net sales and gross margin related to the SARS epidemic in China in 2003. Net loss per share for the years ended December 31, 2004, 2003 and 2002 was $0.30, $0.13 and $0.29, respectively. Weighted average shares outstanding for the year ending December 31, 2004, 2003 and 2002 were 44,626,337, 39,568,199 and 35,002,003, respectively. The increases in the shares outstanding are primarily due to financing activities in 2003 and 2002.

Income Taxes

At December 31, 2004, we had net operating loss carryforwards for federal income tax purposes of approximately $104,000,000 which expire in the years 2006 through 2024. The difference between the cumulative losses for financial reporting purposes and federal income tax purposes is primarily attributable to losses incurred by our foreign subsidiaries. At December 31, 2004, we had federal tax credit carryforwards of approximately $5,000,000 which expire in the years 2009 through 2024.

Because of the "change in ownership" provisions of the Internal Revenue Code, a portion of our net operating loss carryforwards and tax credit carryforwards may be subject to an annual limitation regarding their utilization against taxable income in future periods. As a result of the annual limitation, a portion of these carryforwards may expire before ultimately becoming available to reduce future income tax liabilities.

Liquidity and Capital Resources

At December 31, 2004, 2003 and 2002, we had $51,299,000, $62,975,000 and $21,150,000, respectively, in cash, cash equivalents and short-term investments. In each of these years, the principal factors affecting these balances were the net loss and cash provided by financing activities. We currently estimate cash, cash equivalents and short-term investments at December 31, 2005 will be lower than the balance at December 31, 2004. The expected decrease in this balance is attributable to an expected net loss and the assumption that the $4 million convertible note due December 2005 will be repaid rather than converted. The short-term investments consist primarily of highly liquid marketable securities. We have two letters of credit each secured by a certificate of deposit. At December 31, 2004, the letters of credit totaled $700,000, one for $633,000 under our lease agreement, the other for $67,000 to facilitate our value added tax filings in Europe.

Net cash used in operating activities totaled $12,335,000, $8,055,000 and $5,890,000 for the years ended December 31, 2004, 2003 and 2002, respectively. Net cash used in operating activities for the year ended December 31, 2004 was less than the net loss primarily due to a $1,599,000 decrease in inventory levels. Net cash used in operating activities for the year ended December 31, 2003 was more than the net loss primarily due to a $2,347,000 increase in inventory levels to provide an uninterrupted supply of ZADAXIN as we transferred production to a new contract manufacturer. Net cash used in operating activities for the year ended December 31, 2002 was less than the net loss primarily due to the receipt of a payment from Sigma-Tau for a clinical trial collaboration which increased deferred revenue balances by $2,014,000, and due to increases in accounts payable of $1,576,000 partially offset by increases in prepaid expenses and other assets of $967,000 mostly associated with our phase 3 clinical trials in the United States.

Net cash provided by investing activities is primarily the net result of purchases and sales of short-term investments to provide working capital for operations. We purchased $196,000 of property and equipment during the year ended December 31, 2004.

Net cash provided by financing activities totaled $289,000, $50,074,000 and $10,577,000 for the years ended December 31, 2004, 2003 and 2002, respectively. Net cash provided by financing activities for the year ended December 31, 2004 consisted of approximately $12,000 related to exercises of outstanding options under our employee stock option plans and $277,000 from the issuance of common stock under our employee stock purchase plan. Net cash provided by financing activities for the year ended December 31, 2003 consisted of approximately $44,426,000 from a public offering of common stock, approximately $2,536,000 from the exercise of outstanding warrants to purchase common stock by institutional and accredited investors, approximately $1,800,000 from the issuance of common stock to Sigma-Tau, approximately $1,050,000 related to exercises of outstanding options under our employee stock option plans and $262,000 from the issuance of common stock under our employee stock purchase plan. Net cash provided by financing activities for the year ended December 31, 2002 consisted of approximately $9,914,000 from a direct offering of common stock to institutional investors, approximately $514,000 related to exercises of outstanding options under our employee stock option plans and $149,000 from the issuance of common stock under our employee stock purchase plan.

The following table summarizes our contractual obligations and other commitments as of December 31, 2004.

	Payments Due by Period				
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Convertible notes payable (1)	$ 5,960,000	$ 4,336,000	$ 1,624,000	$ —	$ —
Operating leases (2)	3,623,000	1,396,000	2,198,000	29,000	—
Purchase obligations (3)	6,456,000	3,542,000	2,914,000	—	—
Royalty Obligations (4)	1,020,000	420,000	540,000	40,000	20,000
Total	$ 17,059,000	$ 9,694,000	$ 7,276,000	$ 69,000	$ 20,000

(1) $4,000,000 of these convertible notes mature in December 2005 and $1,600,000 mature in March 2006. See note 7 of the consolidated financial statements. Included in the amounts above is $360,000 for interest payments.

(2) These are future minimum rental commitments for office space and copiers leased under non-cancelable operating lease arrangements.

(3) This includes approximately $1,173,000 in minimum purchase requirement from a contract manufacturer, approximately $1,633,000 in research and development fees payable to the contract research organization under our agreement for the U.S. phase 3 hepatitis C clinical trials, and approximately $3,650,000 to our European marketing and development partner, Sigma-Tau to conduct and complete a hepatitis C clinical trial in Europe.

(4) This includes $20,000 per year through 2010 in minimum royalty payments to the U.S. Army and $900,000 of non-cancelable prepaid royalties to be paid to Wayne State University. Upon regulatory approval of ZADAXIN and commercialization of the product, the Company is obligated to pay the U.S. Army and Wayne State University a royalty based on a percentage of ZADAXIN sales. See note 8 of the Notes to Consolidated Financial Statements.

We intend to give priority use of our financial resources to ZADAXIN clinical programs in the United States. We believe our existing capital resources and funds from product sales are sufficient to complete our current U.S. phase 3 clinical trials and, if the trials are successful and we receive FDA approval, to begin commercialization of ZADAXIN in the United States. However, we cannot assure you that such funds will be sufficient, or that sales of ZADAXIN, if approved in the United States, will result in profitable operations. If we need to raise additional financing, the unavailability or the inopportune timing of any financing could prevent or delay our long-term product development and commercialization programs, either of which would severely hurt our business. The need, timing and amount of any such financing would depend upon numerous factors, including the level of ZADAXIN sales, the timing and amount of manufacturing costs related to ZADAXIN, the availability of complementary products, technologies and businesses, the initiation and continuation of preclinical and clinical trials and testing, the timing of regulatory approvals, developments in relationships with existing or future collaborative parties and the status of competitive products.

There are no officers or directors that were involved in related party transactions in 2004.

Off-Balance Sheet Arrangements

There are no off-balance sheet arrangements in 2004, 2003 or 2002.

Recent Accounting Pronouncement

In December 2004, the Financial Accounting Standards Board ("FASB") issued FASB Statement No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123R") which revises SFAS 123, and supersedes APB 25, and its related implementation guidance. Generally the approach in SFAS 123R is similar to the approach described in SFAS 123. However, SFAS 123R requires share-based payments to employees and directors, including grants of stock options, to be recognized in the statement of operations based on their fair values. Pro forma disclosure is no longer an alternative. The amount of compensation cost will be measured based on the grant-date fair value of the instruments issued. Compensation cost will be recognized over the period that an employee or director provides service in exchange for the award. We expect to adopt SFAS 123R on July 1, 2005.

As permitted by SFAS 123, the Company currently accounts for share-based payments to employees and directors using APB 25's intrinsic value method and, as such, generally recognizes no compensation cost for employee and director stock options. Accordingly, the adoption of SFAS 123R's fair value method will have a significant impact on our result of operations, although it will have no impact on our overall financial position. The impact of adoption of SFAS 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had we adopted SFAS 123R in prior periods, the impact of that standard would have approximated the impact of SFAS 123 as described in the disclosure of pro forma net loss and net loss per share in the Accounting for Stock-Based Compensation section of Note 1 to our consolidated financial statements.

Risk Factors

You should carefully consider the risks described below, in addition to the other information in this report on Form 10-K, before making an investment decision. Each of these risk factors could adversely affect our business, financial condition, and operating results as well as adversely affect the value of an investment in our common stock.

If we are unable to commercialize ZADAXIN in various markets for multiple indications, particularly in the United States for the treatment of HCV, our business will be harmed.

Our ability to achieve and sustain operating profitability depends in large part on our ability to commence, execute and complete clinical programs and obtain additional regulatory approvals for ZADAXIN and other drug candidates, particularly in the United States, Europe and Japan. We are also dependent on our ability to increase ZADAXIN sales in existing markets and launch ZADAXIN in new markets. In particular, our ability to achieve and sustain profitability will depend in large part on our ability to commercialize ZADAXIN for the treatment of HCV in the United States. We cannot assure you that we will achieve significant levels of sales or that we will receive approval for ZADAXIN for the treatment of HCV in the United States or for the treatment of HCV or other indications in other countries. If we are unable to do so, our business will be harmed.

If we do not obtain regulatory approval for ZADAXIN for the intended indications that we are evaluating, our revenues will be limited and we will not become profitable.

Our ability to execute on our business strategy requires that we obtain regulatory approval for the use of ZADAXIN, particularly for the treatment of HCV in the United States and both HCV and malignant melanoma in Europe. If our current phase 3 trials in the United States and current and future trials in Europe yield favorable results, we intend to submit applications for marketing approval of ZADAXIN for the treatment of HCV in the United States and through our partner, Sigma-Tau, for the treatment of HCV and malignant melanoma in Europe. The regulatory approval processes in the United States and Europe are demanding and typically require 12 months or more in the United States and 18 months or more in Europe from the date of submission of an NDA. We have committed significant resources, including capital and time, to develop ZADAXIN, particularly for HCV in the United States, with the goal of obtaining such approvals. If we do not obtain these approvals, we will be unable to achieve any substantial increase in our revenue from ZADAXIN and our ZADAXIN sales in other jurisdictions could decline.

All new drugs, including our products, which have been developed or are under development, are subject to extensive and rigorous regulation by the FDA and comparable agencies in state and local jurisdictions and in foreign countries. These regulations govern, among other things, the development, testing, manufacturing, labeling, storage, pre-market approval, importation, advertising, promotion, sale and distribution of our products. These regulations may change from time to time and new regulations may be adopted.

Obtaining regulatory approval in developing countries also is time-consuming and expensive. In some countries where we are contemplating marketing and selling ZADAXIN, the regulatory approval process often relies on prior approvals obtained in the United States or in Europe. Without such prior approvals, our ability to obtain regulatory approvals for ZADAXIN in these countries may be delayed or prevented. In addition, to secure these regulatory approvals, we will need, among other things, to demonstrate favorable results from additional clinical trials of ZADAXIN. Even if we are able to complete the clinical trials we have sponsored or are planning in a timely or cost-effective manner, these trials may not fulfill the applicable regulatory approval criteria, in which case we will not be able to obtain regulatory approval in these countries, and we have experienced difficulties in preparing for regulatory approval in Japan. We cannot assure you that we will ultimately obtain regulatory approvals in our targeted countries in a timely and cost-effective manner or at all. If we fail to obtain the required regulatory approvals to develop, market and sell our products in countries where we currently do not have such rights, our revenues will be limited.

Satisfaction of government regulations may take several years and the time needed to satisfy them varies substantially based on the type, complexity and novelty of the pharmaceutical product. As a result, government regulation may cause us to delay the introduction of, or prevent us from marketing, our existing or potential products for a considerable period of time and impose costly procedures upon our activities. Even if we obtain regulatory approval for our products, such approval may impose limitations on the indicated uses for which our products may be marketed. Unsatisfactory data resulting from clinical trials may also adversely affect our ability to market and sell ZADAXIN in markets where it is approved for sale.

If the results of our clinical trials are not favorable, we will be unable to obtain regulatory approval for the intended indications we are evaluating.

To obtain regulatory approvals, we must, among other requirements, complete carefully controlled and well-designed clinical trials demonstrating that a particular drug is safe and effective for the applicable disease. We cannot depend on data from prior trial results to predict or demonstrate that our potential drug products are safe and efficacious under regulatory guidelines to qualify for commercial sale. We cannot assure you, nor can you rely on our previous clinical trial results to predict, that our ongoing or future clinical trials will yield favorable results. Adverse or inconclusive clinical results would prevent us from filing for regulatory approval of ZADAXIN (thymosin alpha 1) for the indications that we are evaluating, and our current programs in those areas would fail. In the past, Alpha 1 Biomedical, from which we acquired certain rights to thymosin alpha 1, conducted a phase 3 clinical trial of thymosin alpha 1 as a therapy for HBV that did not produce statistically significant results and Alpha 1 Biomedical did not submit an NDA to the FDA.

We are currently conducting phase 3 clinical trials based on the use of ZADAXIN in combination with pegylated interferon alpha for the treatment of HCV patients who did not previously respond to treatment. We cannot assure you that these phase 3 clinical trials will yield sufficient or adequate data to demonstrate appropriate safety and efficacy under FDA guidelines. Any failure to obtain sufficient or adequate data could delay or prevent us from securing FDA approval.

Our two phase 3 HCV clinical trials in the United States have been designed to show that the combination of ZADAXIN and pegylated interferon alpha adds a significant clinical benefit when compared to the use of pegylated interferon alpha alone in non-responders. We cannot assure you that the results of this combination therapy will yield the favorable results we expect, or that the independent use of pegylated interferon alpha will not perform better than anticipated, which could reduce the chances that an NDA will be approved or that we will submit an NDA based on such results. If the combination therapy of ZADAXIN and pegylated interferon alpha causes significant adverse side effects beyond those caused by pegylated interferon alpha alone, our clinical trials could be delayed, we may be forced to halt the trials or the FDA may reject an NDA due to safety issues. If any of the foregoing occurs, our efforts to market and sell ZADAXIN in the United States will be significantly impaired, our business will suffer and the price of our stock may decline.

The results and documentation of the hepatitis B clinical trials for ZADAXIN in Japan may not be sufficient to obtain Japanese regulatory approval.

Despite the favorable data from our phase 3 hepatitis B clinical trial in Japan, we have identified problems in meeting the requirements for filing a Japanese New Drug Application (JNDA) for ZADAXIN. A JNDA filing requires complete documentation from all phases of the clinical trials. The phase 1 and phase 2 clinical trials, and part of the phase 3 clinical trials, were conducted and sponsored by Schering Plough KK (SPKK), a pharmaceutical company in Japan, under a development agreement with SciClone. After several months of soliciting from SPKK the data and documentation necessary to proceed with the filing in Japan, and after receiving some additional documentation, we have determined that certain information and documentation from earlier stages of the development process has still not been delivered. Furthermore, we are concerned that some of the necessary documentation may not be available at all, and that certain administrative formalities may not have been observed in the drug development process. If the necessary documentation can be obtained or reproduced in the near future, we intend to proceed with the JNDA. We are reviewing our legal rights and remedies with respect to third parties. We continue to seek a resolution of this matter with SPKK.

Higher than anticipated patient drop out rates in our clinical trials could make it more difficult to obtain regulatory approval.

Each of our two current phase 3 HCV clinical trials in the United States enrolled more than the planned number of 500 patients, one trial treating patients with no liver damage and the other trial treating patients with mild cirrhosis of the liver. The trials require patient treatment for 48 weeks and a follow-up observation period for an additional 24 weeks. Patient dropouts were expected, but have been higher than anticipated. A patient who drops out at any point in the 72 weeks of the trial is considered a "failure to respond" in results of the clinical trial. Dropouts will not prevent us from completing our trials, however, the fewer patients who

complete the trial, in general, the higher the positive response rate for the group of remaining ZADAXIN treated patients needs to be to demonstrate statistical significance. Therefore, a higher than anticipated dropout rate lowers our chances of proving statistical significance which could adversely effect our preparation of an NDA.

We cannot predict the safety profile of the use of ZADAXIN when used in combination with other drugs.

Many of our trials involve the use of ZADAXIN in combination with other drugs. Some of these drugs are known to cause adverse patient reactions. Even if ZADAXIN does not produce adverse side effects when used alone, we cannot predict how it will work with other drugs, including causing possible adverse side effects not directly attributable to the other drugs that could compromise the safety profile of ZADAXIN when used in certain combination therapies.

If we lose key personnel or are unable to attract and retain additional, highly skilled personnel required for the expansion of our activities, our business will suffer. Our Board of Directors is conducting a search for a new Chief Executive Officer.

We are highly dependent upon our ability to attract and retain qualified personnel because of the specialized, scientific and worldwide nature of our business. Following the departure of our Chief Executive Officer on July 14, 2004, we established an Office of the President, and believe that the Company will function effectively while we work to identify a new Chief Executive Officer. However, we may still be affected adversely, particularly if we cannot retain a new Chief Executive Officer in a reasonable time frame. There is intense competition for qualified management, scientific and technical personnel in the pharmaceutical industry, and we may not be able to attract and retain the qualified personnel we need to grow and develop our business globally. In addition, we assign numerous key responsibilities to a limited number of individuals, and we would experience difficulty in finding immediate replacements for any of them. If we were unable to attract and retain qualified personnel as needed or promptly replace those employees who are critical to our product development and commercialization, the development and commercialization of our products would be adversely affected. At this time, we do not maintain "key person" life insurance on any of our key personnel.

Our revenue is dependent on the sale of ZADAXIN in foreign countries, particularly China, and if we experience difficulties in our foreign sales efforts, our financial condition will be harmed.

Our product revenue in the near term is highly dependent on the sale of ZADAXIN in foreign countries. If we experience difficulties in our foreign sales efforts, our business will suffer and our financial condition will be harmed. Substantially all of our ZADAXIN sales are to customers in China. Sales of ZADAXIN in China may be limited due to the low average personal income, lack of patient cost reimbursement, poorly developed infrastructure and existing and potential competition from other products, including generics. In China, ZADAXIN is approved only for the treatment of HBV. We face competition from certain large, global pharmaceutical companies who are aggressively marketing competing products for the treatment of HBV and other indications where ZADAXIN is used on an off-label basis. In addition, several local companies have introduced lower priced locally manufactured generic thymosin. We expect such competition to continue and there could be a negative impact on the price and the volume of ZADAXIN sold in China, which would harm our business.

Our ZADAXIN sales and operations in other parts of Asia, as well as in Latin America and the Middle East, are subject to a number of risks, including difficulties and delays in obtaining registrations, permits, pricing approvals and reimbursement and unexpected changes in regulatory requirements. We experience other issues with managing foreign sales operations including long payment cycles, difficulties in accounts receivable collection and, especially from significant customers, fluctuations in the timing and amount of orders. Operations in foreign countries also expose us to risks relating to difficulties in enforcing our proprietary rights, currency fluctuations and adverse or deteriorating economic conditions.

We do not have product sales in the United States, Europe or Japan with which to offset any decrease in our revenue from ZADAXIN sales in Asia, Latin America and the Middle East. In addition, some countries in these regions, including China, regulate pharmaceutical prices and pharmaceutical importation. These regulations may reduce prices for ZADAXIN to levels significantly below those that would prevail in an unregulated market, limit the volume of product which may be imported and sold or place high import duties on the product, any of which may limit the growth of our revenues or cause them to decline.

Because of China's tiered method of importing and distributing finished pharmaceutical products, our quarterly results may vary substantially from one period to the next.

China uses a tiered method to import and distribute finished pharmaceutical products. At each port of entry, and prior to moving the product forward to the distributors, government-licensed importing agents must process and evaluate each shipment to determine

whether such shipment satisfies China's quality assurance requirements. In order to efficiently manage this process, the importing agents typically place large, and therefore relatively few, orders within any six month period. Therefore, our sales to an importing agent can vary substantially from quarter to quarter depending on the size and timing of the orders, which has in the past and may in the future cause our quarterly results to fluctuate. We rely on four to six importers, in any given quarter, to supply substantially all of our product in China. Because we use a small number of importing agents in China, our receivables from any one importing agent are material, and if we were unable to collect receivables from any importer, our business and cash-flow would be adversely affected.

Our sales of ZADAXIN may fluctuate due to seasonality of product orders and sales in any quarter may not be indicative of future sales.

Our sales for the quarter ended June 30, 2003 were greatly affected by the demand in China for ZADAXIN in connection with the treatment of SARS. To date, SARS has not re-emerged, like influenza, as a seasonal public health problem. However, if SARS or a similar epidemic were to emerge, it is not possible to predict what effect, if any, this would have on future sales of ZADAXIN. Although we do not market ZADAXIN for use in treating such epidemic diseases, if ZADAXIN is purchased in connection with future outbreaks of seasonal viral contagions, product sales could become more concentrated in certain quarters of the calendar year, quarterly sales levels could fluctuate and sales in any quarter may not be indicative of sales in future periods.

If we fail to protect our products, technologies and trade secrets, we may not be able to successfully use, manufacture, market or sell our products, or we may fail to advance or maintain our competitive position.

Our success depends significantly on our ability to obtain and maintain meaningful patent protection for our products and technologies and to preserve our trade secrets. Our pending patent applications may not result in the issuance of patents in the future. Our patents or patent applications may not have priority over others' applications. Our existing patents and additional patents that may be issued, if any, may not provide a competitive advantage to us or may be invalidated or circumvented by our competitors. Others may independently develop similar products or design around patents issued or licensed to us. Patents issued to, or patent applications filed by, other companies could harm our ability to use, manufacture, market or sell our products or maintain our competitive position with respect to our products. Although many of our patents relating to ZADAXIN have expired, including composition of matter patents, we have rights to other patents and patent applications relating to ZADAXIN and ZADAXIN analogues, including method of use patents with respect to the use of ZADAXIN for certain indications. If other parties develop generic forms of ZADAXIN for other indications, including conducting clinical trials for such indications, our patents and other rights might not be sufficient to prohibit them from marketing and selling such generic forms of ZADAXIN. If other parties develop analogues or derivatives of ZADAXIN, our patents and other rights might not be sufficient to prohibit them from marketing these analogues or derivatives.

Pharmaceutical products are either not patentable or have only recently become patentable in some of the countries in which we market or may market ZADAXIN. We do not have patent protection for ZADAXIN in China, our largest market. Other companies market generic thymosin alpha 1 in China, sometimes in violation of our trademark or other rights which we defend by informing physicians and hospitals of the practice as well as through the limited legal recourse. Past enforcement of intellectual property rights in many of these countries, including China in particular, has been limited or non-existent. Future enforcement of patents and proprietary rights in many other countries will likely be problematic or unpredictable. Moreover, the issuance of a patent in one country does not assure the issuance of a similar patent in another country. Claim interpretation and infringement laws vary by nation, so the extent of any patent protection is uncertain and may vary in different jurisdictions.

If we are involved in intellectual property claims and litigation, the proceedings may divert our resources and subject us to significant liability for damages, substantial litigation expense and the loss of our proprietary rights.

Our commercial success depends in part on us not infringing valid, enforceable patents or proprietary rights of third parties, and not breaching any licenses that may relate to our technologies and products. We are aware of a third-party patent that may relate to our products and may cover a method of action used by ZADAXIN. We cannot assure you that our mechanism of action does not infringe on their claim. In addition, we may not be aware of all patents or patent applications that may impact our ability to make, use or sell any of our potential products. For example, U.S. patent applications may be kept confidential for 12 or more months while pending in the Patent and Trademark Office, and patent applications filed in foreign countries are often first published six months or more after filing. It is possible that we may unintentionally infringe these patents or other patents or proprietary rights of third parties. We may in the future receive notices claiming infringement from third parties as well as invitations to take licenses under third-party patents. Any legal action against us or our collaborative partners claiming damages and seeking to enjoin commercial activities relating to our products and processes affected by third-party rights may require us or our collaborative partners to obtain licenses in order to continue to manufacture or market the affected products and processes. Our efforts to defend against any of these claims, regardless of

merit, would require us to devote resources and attention that could have been directed to our operations and growth plans. In addition, these actions may subject us to potential liability for damages. We or our collaborative partners may not prevail in a patent action and any license required under a patent may not be made available on commercially acceptable terms, or at all. Any conflicts resulting from the patent rights of others could significantly reduce the coverage of our patents and limit our ability to obtain meaningful patent protection.

If other companies obtain patents with conflicting claims, we may be required to obtain licenses to those patents or develop or obtain alternative technology to manufacture or market the affected products and processes. We may not be able to obtain any such licenses on acceptable terms or at all. Any failure to obtain such licenses could delay or prevent us from pursuing the development or commercialization of our potential products. Our efforts to defend against any of these claims would require us to devote resources and attention that could have been directed to our operations and growth plans.

We may need to initiate litigation, which could be time-consuming and expensive, to enforce our proprietary rights or to determine the scope and validity of others' rights. If litigation results, a court may find our patents or those of our licensors invalid or may find that we have infringed on a competitor's rights. If any of our competitors have filed patent applications in the United States which claim technology we also have invented, the Patent and Trademark Office may require us to participate in expensive interference proceedings to determine who has the right to a patent for the technology. These actions may subject us to potential liability for damages. We or our collaborative partners may not prevail in a patent action and any license required under a patent may not be made available on commercially acceptable terms, or at all.

We rely on third parties to supply our clinical trial and commercial products. Deficiencies in their work could delay or harm one or more important areas of our business including our sales, clinical trials or the regulatory approval process.

We rely on third parties, who are subject to regulatory oversight, to supply our clinical and commercial products. If unanticipated deficiencies in these suppliers occur, we could experience delays in our ability to assemble a timely and acceptable NDA. If sales of ZADAXIN were to increase dramatically, our third-party suppliers may not be able to supply ZADAXIN quickly enough, which could limit our ability to satisfy increased demand or could adversely affect the ability of these suppliers to provide products for our clinical trials. Roche is our exclusive supplier of pegylated interferon alpha for our current U.S. phase 3 HCV clinical trials and we have received all the pegylated interferon to be used in these clinical trials. Any recall of pegylated interferon alpha could delay the clinical trials or detract from the integrity of the trial data, in which case, Roche’s ability to complete our clinical trials in the United States and to market and sell ZADAXIN worldwide will be delayed or impaired, our business will suffer and the price of our stock may decline. We have been in the process of qualifying a new manufacturer of ZADAXIN and if we encounter problems with this process of validation, our sales or our clinical trials could be adversely affected.

If we are not able to establish and maintain adequate manufacturing relationships, the development and sale of our products could be impaired.

To be successful, our products must be manufactured in commercial quantities, in compliance with stringent regulatory requirements and at an acceptable cost. Typically we have at any time only one supplier for each phase of manufacturing of our product. Manufacturing interruptions or failure to comply with regulatory requirements could significantly delay clinical development of potential products and reduce third-party or clinical researcher interest and support of proposed trials. These interruptions or failures could also impede commercialization of our products, including sales of ZADAXIN in approved markets, and impair our competitive position. Any of these developments would harm our business.

We are in the process of qualifying a new supplier for ZADAXIN with regulatory agencies. This process, quality assurance and other steps could cause delays or interruptions of supply. If we do not obtain the required regulatory approvals for a manufacturing change in a timely fashion, especially in China, our sales may be interrupted until the manufacturing change is approved. Although we are increasing inventories to prepare to manage any such occurrences, we may still experience interruptions in supply which could adversely affect our results.

In some countries, a manufacturing change may require additional regulatory approvals which may delay ZADAXIN marketing approvals in new markets.

In addition, manufacturing, supply and quality control problems may arise as we, either alone or with subcontractors, attempt to scale-up our manufacturing procedures. We may not be able to scale-up in a timely manner or at a commercially reasonable cost, either of which could cause delays or pose a threat to the ultimate commercialization of our products and harm our business.

We may not be able to successfully develop or commercialize our products. We may consider strategic alliances with other companies in efforts to broaden our product development pipeline.

While we have limited sales of ZADAXIN in certain markets, we do not yet have regulatory approval for ZADAXIN for our principal target markets, and, in this respect, ZADAXIN is still being developed. Our other potential products are in earlier stages of development than ZADAXIN. We may consider and undertake various strategies to expand our portfolio of potential products, including acquiring product candidate rights through licenses or other relationships, or through other strategic relationships including acquisitions of other companies that may have proprietary rights to other development candidates or the capability to discover new drug candidates. Such transactions could require a substantial amount of our financial resources, or, if equity is involved, may result in substantial dilution to current stockholders. Strategic transactions also require substantial management time and effort and are subject to various risks that could adversely affect us or our financial results.

To fully develop our products, we will need to commit substantial resources to extensive research, development, pre-clinical testing, clinical trials, manufacturing scale-up and regulatory approval prior to being ready for sale. We cannot assure that our efforts will produce commercially viable products. We face significant technological risks inherent in developing these products. We may also abandon some or all of our proposed products before they become commercially viable. If any of our products, even if developed and approved, cannot be successfully commercialized in a timely manner, our business will be harmed and the price of our stock may decline.

We have not yet sold any product other than ZADAXIN and our sales have been primarily in a single country, China. Our future revenue growth depends on increased market acceptance and commercialization of ZADAXIN in additional countries, particularly in the United States, Europe and Japan. If we fail to successfully market ZADAXIN, or if we cannot commercialize this drug in the United States and other additional markets, our revenue and operating results will suffer. If unexpected and serious adverse events are reported, or if expected efficacy results are not achieved, it would have a material adverse effect on our business. Our future revenue will also depend in part on our ability to develop other commercially viable and accepted products. Market acceptance of our products will depend on many factors, including our ability to convince prospective customers to use our products as an alternative to other treatments and therapies and to convince prospective strategic partners to market our products effectively and to manufacture our products in sufficient quantities with acceptable quality and at an acceptable cost. In addition, doctors must opt to use treatments involving our products. If doctors elect to use a different course of treatment, demand for our drug products would be reduced. Failure to do any of the above will lead to an unfavorable outcome on the results of our operations.

We rely on third-party clinical investigators to conduct our clinical trials and, as a result, we may encounter delays outside our control.

We have limited experience in conducting and managing clinical trials and we rely, in part, on third parties, particularly clinical research organizations and our development partners, to assist us in managing and monitoring clinical trials. Our reliance on these third parties may result in delays in completing, or failure to complete, these clinical trials if third parties fail to fulfill their obligations to us.

We may need to obtain additional capital to support our long-term product development and commercialization programs.

We believe our existing resources will be sufficient to complete our current U.S. phase 3 clinical trials and, if the trials are successful and we receive FDA approval, to begin commercialization of ZADAXIN in the United States. However, we cannot assure that such funds will be sufficient, or that sales of ZADAXIN, if approved in the United States, will result in profitable operations. In addition, we may need additional funds in the future to support future growth and achieve profitability. If we need to raise additional funds in the future and such funds are not available on reasonable terms, if at all, our commercialization efforts may be impeded, our revenues may be limited and our operating results may suffer.

We have a history of operating losses and an accumulated deficit. We expect to continue to incur losses in the near term and may never achieve profitability.

We have experienced significant operating losses since our inception, and as of December 31, 2004, we had an accumulated deficit of approximately $152 million. We expect our operating expenses to increase over the next several years as we plan to dedicate substantially all of our resources to expanding our development, testing and marketing capabilities, particularly in the United States, and these losses may increase if we cannot increase or sustain revenue. As a result, we may never achieve profitability.

We have limited sales, marketing and distribution capabilities, which may adversely affect our ability to successfully commercialize our products.

We currently have limited sales, marketing and distribution capabilities, and we anticipate that we may be relying on third-party collaborators to sell, market and distribute our products for the foreseeable future. If our arrangements with these third parties are not successful, or if we are unable to enter into additional third-party arrangements, we may need to substantially expand our sales, marketing and distribution force. Our efforts to expand may not succeed, or we may lack sufficient resources to expand in a timely manner, either of which will harm our operating results. Moreover, if we are able to further expand our sales, marketing and distribution capabilities, we will begin competing with other companies that have experienced and well-funded operations. If we cannot successfully compete with these larger companies, our revenues may not grow and our business may suffer.

Commercialization of some of our products depends on collaborations with others. If our collaborators are not successful, or if we are unable to find future collaborators, we may not be able to properly develop and commercialize our products.

We depend in part on our distributors and business partners to develop and/or promote our drugs, and if they are not successful in their efforts or fail to do so, our business will suffer. For example, Sigma-Tau is responsible for the development and marketing of ZADAXIN in Europe. We generally do not have control over the amount and timing of resources that our business partners devote to ZADAXIN, and they have not always performed as or when expected. If they do not perform their obligations as we expect, particularly obligations regarding clinical trials, our development expenses would increase and the development and/or sale of our products could be limited or delayed, which could hurt our business and cause our stock price to decline. In addition, our relationships with these companies may not be successful. Disputes may arise with our collaborators, including disputes over ownership rights to intellectual property, know-how or technologies developed with our collaborators. We may not be able to negotiate similar additional arrangements in the future to develop and commercialize ZADAXIN or other products.

We may lose market share or otherwise fail to compete effectively in the intensely competitive biopharmaceutical industry.

Competition in the biopharmaceutical industry is intense, and we expect that competition will increase. Our success depends on our ability to compete in this industry, but we cannot assure you that we will be able to successfully compete with our competitors. Increased competitive pressure could lead to intensified price-based competition resulting in lower prices and margins, which would hurt our operating results.

We are focused on developing ZADAXIN as a treatment for HCV and HBV and certain cancers. Several large biopharmaceutical companies have substantial commitments to interferon alpha, an approved drug for treating HBV and HCV, and to lamivudine and adefovir, approved drugs to treat HBV. We cannot assure you that we will compete successfully against our competitors or that our competitors, or potential competitors, will not develop drugs or other treatments for HCV, HBV, cancer and other diseases that will be superior to ours.

If third-party reimbursement is not available or patients cannot otherwise pay for ZADAXIN, we may not be able to successfully market ZADAXIN.

Significant uncertainty exists as to the reimbursement status of new therapeutic products, such as ZADAXIN. We cannot assure you that third-party insurance coverage and reimbursement will be available for therapeutic products we might develop. The failure to obtain third-party reimbursement for our products, particularly in the United States, Europe and Japan, would harm our business. Further, we cannot assure you that additional limitations will not be imposed in the future in the United States on drug coverage and reimbursement due to proposed health care reforms. In many emerging markets where we have marketing rights to ZADAXIN, but where government resources and per capita income may be so low that our products will be prohibitively expensive, we may not be able to market our products on economically favorable terms, if at all.

Efforts by governmental and third-party payers to contain or reduce health care costs or the announcement of legislative proposals or reforms to implement government controls could cause us to reduce the prices at which we market our drugs, which will reduce our gross margins and may harm our business.

We may be subject to product liability lawsuits, and our insurance may be inadequate to cover damages.

Clinical trials or marketing of any of our current and potential products may expose us to liability claims from the use of these products. We currently carry product liability insurance. However, we cannot be certain that we will be able to maintain insurance on

acceptable terms, if at all, for clinical and commercial activities or that the insurance would be sufficient to cover any potential product liability claim or recall. If we fail to have sufficient coverage, our business, results of operations and cash flows could be adversely affected.

We depend on international sales, and global conditions could negatively affect our operating results.

A large majority of our sales are in China. Heightened tensions resulting from the current geopolitical conditions in the Middle East, North Korea and elsewhere could worsen, causing disruptions in foreign trade, which would harm our sales. In particular, our commercial product is manufactured in Europe and distributed by us from our operations in Hong Kong. Any disruption of our supply and distribution activities due to geopolitical conditions could decrease our sales and harm our operating results.

If we are unable to comply with environmental and other laws and regulations, our business may be harmed.

We are subject to various federal, state and local laws, regulations and recommendations relating to the use, manufacture, storage, handling and disposal of hazardous materials and waste products (including radioactive compounds and infectious disease agents), as well as safe working conditions, laboratory and manufacturing practices and the experimental use of animals. The extent of government regulation that might result from future legislation or administrative action in these areas cannot be accurately predicted.

We do not currently maintain hazardous materials at our facilities. While we outsource our research and development programs involving the controlled use of biohazardous materials, if in the future we conduct these programs ourselves, we might be required to incur significant cost to comply with environmental laws and regulations. Further, in the event of an accident, we would be liable for any damages that result, and the liability could exceed our resources.

Our stock price may be volatile, and an investment in our stock could suffer a decline in value.

The market price of our common stock has experienced, and may continue to experience, substantial volatility due to many factors, some of which we have no control over, including:

- progress and results of clinical trials involving ZADAXIN;
- progress of ZADAXIN through the regulatory process, especially regulatory actions and the adequacy of clinical data and documentation for regulatory purposes in the United States, Europe and Japan;
- timing and achievement of milestones;
- announcements of technological innovations or new products by us or our competitors;
- government regulatory action affecting our drug products or our competitors' drug products in both the United States and foreign countries;
- developments or disputes concerning patent or proprietary rights;
- changes in company assessments or financial estimates by securities analysts;
- actual or anticipated fluctuations in our quarterly operating results;
- general stock market conditions and fluctuations for the emerging growth and biopharmaceutical market sectors;
- economic conditions in the United States or abroad; and
- broad financial market fluctuations in the United States, Europe or Asia.

In the past, following periods of large price declines in the public market price of a company's securities, securities class action litigation has often been initiated against that company. Litigation of this type could result in substantial costs and diversion of our attention and resources, which would hurt our business. Any adverse determination in litigation could also subject us to significant liabilities.

Substantial sales of our stock or the exercise or conversion of options or convertible securities may impact the market price of our common stock.

As of December 31, 2004, stock options to purchase 6,706,613 shares of common stock were outstanding, of which options to purchase 4,971,804 shares were exercisable. Also outstanding as of the same date were warrants exercisable for 904,760 shares of common stock at $7.00 per share, however, the exercise term of all of these warrants expired in January 2005. As of December 31, 2004 two notes convertible into a total of 684,140 shares of common stock were outstanding. The note holder has the right to purchase up to $8.3 million of additional convertible notes due on or before March 2006, which, if fully issued, will be convertible into 684,140 shares of our common stock. Upon exercise of options or conversion of the notes, these issued shares of common stock will be freely tradable.

Future sales of substantial amounts of our common stock could adversely affect the market price of our common stock. Similarly, if we raise additional funds through the issuance of common stock or securities convertible into or exercisable for common stock, the percentage ownership of our stockholders will be reduced and the price of our common stock may fall.

Sales of our common stock by officers and directors and a former officer could affect our stock price.

Our Board of Directors has approved an amendment to our trading policy that permits officers and directors to enter into trading plans that comply with the requirements of Rule 10b5-1 of the Securities and Exchange Act of 1934. Rule 10b5-1 allows corporate officers and directors to adopt written, pre-arranged stock trading plans when they do not have material, non-public information. Using these plans, officers and directors can gradually diversify their investment portfolios, can spread stock trades out over an extended period of time to reduce any market impact and can avoid concerns about initiating stock transactions at a time when they might be in possession of material, non-public information. As of March 9, 2005, only one director has adopted such a plan, and other directors or officers may do so in the future. In general our officers and directors have rarely sold stock in the Company, though they have held options or stock for many years. However, the separation of our former Chief Executive Officer from the Company in July 2004 may affect his personal financial plans and result in both his exercising of stock options and selling of stock which may have affected or may in the future affect the trading price of our stock. As of March 9, 2005, the former CEO has 1,610,454 shares of stock options outstanding and exercisable that will expire between April 2005 and July 2006. We expect future sales by officers and directors either under 10b5-1 plans or otherwise as a result of their personal financial planning. We do not believe the volume of such sales would affect our trading price; however, the market could react negatively to sales by our officers and directors, which could affect the trading price of our stock.

Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us, which may be beneficial to our stockholders, more difficult.

Certain anti-takeover provisions of Delaware law and our charter documents as currently in effect may make a change in control of our company more difficult, even if a change in control would be beneficial to the stockholders. Prior to our reincorporation in Delaware, we had a stockholder rights plan, also commonly known as a "poison pill," which we terminated in connection with the reincorporation. We currently do not intend to adopt a stockholder rights plan. However, our charter documents do contain certain anti-takeover provisions, including provisions in our certificate of incorporation providing that stockholders may not cumulate votes, stockholders' meetings may be called by stockholders only if they hold 25% or more of our common stock and provisions in our bylaws providing that the stockholders may not take action by written consent. Additionally, our board of directors has the authority to issue 10 million shares of preferred stock and to determine the terms of those shares of stock without any further action by the stockholders. The rights of holders of our common stock are subject to the rights of the holders of any preferred stock that may be issued. The issuance of preferred stock could make it more difficult for a third-party to acquire a majority of our outstanding voting stock. Delaware law also prohibits corporations from engaging in a business combination with any holders of 15% or more of their capital stock until the holder has held the stock for three years unless, among other possibilities, the board of directors approves the transaction. Our board of directors may use these provisions to prevent changes in the management and control of our company. Also, under applicable Delaware law, our board of directors may adopt additional anti-takeover measures in the future.

New legislation and potential new accounting pronouncements may impact our operations and financial position or results of operations.

Future changes in financial accounting standards, including proposed changes in accounting for stock options, may cause adverse, unexpected fluctuations in the timing of the recognition of revenues or expenses and may affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency and may occur in the

future and we may make changes in our accounting policies in the future. Compliance with changing regulations concerning corporate governance and public disclosure has resulted in and may continue to result in additional expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and NASDAQ National Market rules, are creating uncertainty for companies such as ours and costs are increasing as a result of this uncertainty and other factors. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment has and may continue to result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating product development activities to compliance activities.

New legislation may impact our operations and financial position or results of operations.

Compliance with changing regulations concerning corporate governance and public disclosure has resulted in and may continue to result in additional expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and NASDAQ National Market rules, are creating uncertainty for companies such as ours and costs are increasing as a result of this uncertainty and other factors. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment has and may continue to result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

We may be subject to currency exchange rate fluctuations, which could adversely affect our financial performance.

Substantially all of our product sales are denominated in U.S. dollars. Fluctuation in the U.S. dollar exchange rate with local currency directly affects the customer's cost for our product. In particular, a stronger U.S. dollar vis-à-vis the local currency would tend to have an adverse effect on sales and potentially on collection of accounts receivable. To date, this exposure to currency exchange rate fluctuations has been minimal because the Chinese currency has been pegged to the U.S. dollar. However, the fixed nature of the Chinese currency in relation to the U.S. dollar may not continue in the future and, consequently, our foreign operations may expose us to greater risk of currency exchange rate fluctuations in the future. In addition, we are subject to currency exchange rate fluctuations as a result of expenses incurred by our foreign operations. In particular, one of our supply arrangements under which we purchase finished products is denominated in euros. Consequently, changes in exchange rates could unpredictably and adversely affect our operating results and could result in exchange losses. To date, we have not hedged against the risks associated with fluctuations in exchange rates and, therefore, exchange rate fluctuations could have a material adverse impact on our operating results and stock price.

Item 7A. ***Quantitative and Qualitative Disclosures About Market Risk***

The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest solely in U.S. Treasury or U.S. government agency notes and highly rated, highly liquid short-term municipal securities. Our investments in these notes are subject to interest rate risk. To minimize the exposure due to an adverse shift in interest rates, we invest in short-term notes and maintain an average maturity of less than one year. A hypothetical 60 basis point increase in interest rates would result in an approximate $233,246 decrease (0.6%) in fair value of our available-for-sale securities. This potential change is based on sensitivity analyses performed on our financial position at December 31, 2004. Actual results may differ materially.

Our purchases from one of our contract manufacturers are denominated in euros and this exposes us to foreign currency rate fluctuations. However, substantially all our sales and most of our manufacturing costs to date have been in U.S. dollars.

Item 8. ***Financial Statements and Supplementary Data***

SCICLONE PHARMACEUTICALS, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of SciClone Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of SciClone Pharmaceuticals, Inc. as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2004. Our audits also included the financial statement schedule listed at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of SciClone Pharmaceuticals, Inc. at December 31, 2004 and 2003, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of SciClone Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 10, 2005 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California
March 10, 2005

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of SciClone Pharmaceuticals, Inc.

We have audited management's assessment, included in the accompanying Management's Report on Internal Control over Financial Reporting, that SciClone Pharmaceuticals, Inc. maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). SciClone Pharmaceuticals, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that SciClone Pharmaceuticals, Inc. maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, SciClone Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria**.**

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of SciClone Pharmaceuticals, Inc. as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2004 and our report dated March 10, 2005 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California
March 10, 2005

SCICLONE PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2004	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 41,204,000	$ 52,899,000
Restricted short-term investments	700,000	695,000
Other short-term investments	9,395,000	9,381,000
Accounts receivable, net of allowance of $452,000 in 2004 and $638,000 in 2003	10,279,000	10,142,000
Inventories	4,179,000	5,778,000
Prepaid expenses and other current assets	1,478,000	2,456,000
Total current assets	67,235,000	81,351,000
Property and equipment, net	398,000	325,000
Intangible assets, net	542,000	612,000
Other assets	1,534,000	1,534,000
Total assets	$ 69,709,000	$ 83,822,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,225,000	$ 3,423,000
Accrued compensation and employee benefits	2,177,000	1,440,000
Accrued professional fees	452,000	481,000
Other accrued expenses	917,000	631,000
Accrued clinical trials expense	1,500,000	1,889,000
Deferred revenue	537,000	537,000
Convertible note payable	4,000,000	—
Total current liabilities	11,808,000	8,401,000
Deferred revenue	134,000	671,000
Other long-term liabilities	1,044,000	900,000
Convertible note payable	1,600,000	5,600,000
Commitments and contingencies		
Stockholders' equity:		
Preferred stock; $0.001 par value; 10,000,000 shares authorized; no shares outstanding	—	—
Common stock; $0.001 par value; 75,000,000 shares authorized; 44,677,845 and 44,484,144 shares issued and outstanding in 2004 and 2003, respectively	45,000	44,000
Additional paid-in capital	206,608,000	206,320,000
Accumulated other comprehensive income	38,000	176,000
Accumulated deficit	(151,568,000)	(138,290,000)
Total stockholders' equity	55,123,000	68,250,000
Total liabilities and stockholders' equity	$ 69,709,000	$ 83,822,000

See notes to consolidated financial statements.

SCICLONE PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year ended December 31,		
	2004	2003	2002
Revenues:			
Product sales	$ 22,765,000	$ 31,732,000	$ 17,101,000
Contract revenue	1,631,000	806,000	671,000
Total revenues	24,396,000	32,538,000	17,772,000
Cost of product sales	4,577,000	5,636,000	3,487,000
Gross margin	19,819,000	26,902,000	14,285,000
Operating expenses:			
Research and development	17,994,000	18,949,000	11,647,000
Sales and marketing	9,665,000	9,018,000	8,724,000
General and administrative	6,311,000	4,134,000	3,902,000
Total operating expenses	33,970,000	32,101,000	24,273,000
Loss from operations	(14,151,000)	(5,199,000)	(9,988,000)
Interest and investment income[(1)]	1,285,000	266,000	323,000
Interest expense	(361,000)	(361,000)	(361,000)
Other income (expense), net	(51,000)	19,000	(11,000)
Net loss	$ (13,278,000)	$ (5,275,000)	$ (10,037,000)
Basic and diluted net loss per share	$ (0.30)	$ (0.13)	$ (0.29)
Weighted average shares used in computing basic and diluted net loss per share	44,626,337	39,568,199	35,002,003

(1) For the year ended December 31, 2004, interest and investment income included an approximate gain of $697,000 from sale of equity securities.

See notes to consolidated financial statements.

SCICLONE PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

	Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balance at December 31, 2001	32,474,150	$145,713,000	$ —	$ 39,000	$ (122,978,000)	$22,774,000
Issuance of common stock from exercise of stock options, warrants and employee stock purchase plan	342,306	663,000	—	—	—	663,000
Issuance of common stock from private placements	4,088,460	9,914,000	—	—	—	9,914,000
Net loss	—	—	—	—	(10,037,000)	(10,037,000)
Net unrealized gain on available-for-sale securities	—	—	—	40,000	—	40,000
Total comprehensive loss						(9,997,000)
Balance at December 31, 2002	36,904,916	156,290,000	—	79,000	(133,015,000)	23,354,000
Issuance of common stock from exercise of stock options, warrants and employee stock purchase plan	847,171	3,256,000	—	—	—	3,256,000
Issuance of common stock to Sigma-Tau	504,938	1,800,000	—	—	—	1,800,000
Reincorporation in Delaware	—	(161,308,000)	161,308,000	—	—	—
Issuance of common stock from exercise of stock options, warrants and employee stock purchase plan	227,119	—	592,000	—	—	592,000
Issuance of common stock in secondary offering, net of financing costs	6,000,000	6,000	44,420,000	—	—	44,426,000
Net loss	—	—	—	—	(5,275,000)	(5,275,000)
Net unrealized gain on available-for-sale securities	—	—	—	97,000	—	97,000
Total comprehensive loss						(5,178,000)
Balance at December 31, 2003	44,484,144	44,000	206,320,000	176,000	(138,290,000)	68,250,000
Issuance of common stock from exercise of stock options, warrants and employee stock purchase plan	193,701	1,000	288,000	—	—	289,000
Net loss	—	—	—	—	(13,278,000)	(13,278,000)
Net unrealized loss on available-for-sale securities	—	—	—	(138,000)	—	(138,000)
Total comprehensive loss						(13,416,000)
Balance at December 31, 2004	44,677,845	$ 45,000	$206,608,000	$ 38,000	$ (151,568,000)	$ 55,123,000

See notes to consolidated financial statements.

SCICLONE PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,		
	2004	2003	2002
Operating activities:			
Net loss	$ (13,278,000)	$ (5,275,000)	$ (10,037,000)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	190,000	160,000	531,000
Amortization of deferred financing costs	25,000	25,000	25,000
Other non-cash (income) expense, net	(3,000)	(13,000)	(21,000)
Gain on sale of equity investment	(697,000)	—	—
Changes in operating assets and liabilities:			
Accounts receivable	(137,000)	(866,000)	(484,000)
Inventories	1,599,000	(2,347,000)	628,000
Prepaid expenses and other assets	952,000	(355,000)	(967,000)
Accounts payable and other accrued expenses	(912,000)	345,000	1,576,000
Accrued clinical trials expense	(389,000)	923,000	670,000
Accrued professional fees	(29,000)	(198,000)	46,000
Accrued compensation and employee benefits	737,000	352,000	129,000
Long-term liabilities	144,000	—	—
Deferred revenue	(537,000)	(806,000)	2,014,000
Net cash used in operating activities	(12,335,000)	(8,055,000)	(5,890,000)
Investing activities:			
Purchases of property and equipment	(196,000)	(303,000)	(66,000)
Proceeds from sales of short-term and equity investments	697,000	1,000,000	94,000
Proceeds from maturities of short-term investments	6,000,000	500,000	2,600,000
Payments on purchases of short-term investments	(6,150,000)	(550,000)	(6,600,000)
Net cash provided by (used in) investing activities	351,000	647,000	(3,972,000)
Financing activities:			
Proceeds from issuances of common stock, net	289,000	50,074,000	10,577,000
Net cash provided by financing activities	289,000	50,074,000	10,577,000
Net increase (decrease) in cash and cash equivalents	(11,695,000)	42,666,000	715,000
Cash and cash equivalents, beginning of year	52,899,000	10,233,000	9,518,000
Cash and cash equivalents, end of year	$ 41,204,000	$ 52,899,000	$ 10,233,000
Supplemental disclosures of cash flow information:			
Cash paid for interest	$ 336,000	$ 336,000	$ 336,000
Non-cash investing activities:			
Obligations incurred related to prepaid royalties	$ —	$ 1,200,000	$ —

See notes to consolidated financial statements.

SCICLONE PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 — The Company and Summary of Significant Accounting Policies

The Company

SciClone Pharmaceuticals, Inc. ("SciClone" or the "Company") is a biopharmaceutical company engaged in the development and commercialization of therapeutics to treat life-threatening diseases. The Company's lead product ZADAXIN® is currently being evaluated in two phase 3 hepatitis C clinical trials in the United States. ZADAXIN is also being evaluated in other late-stage clinical trials for the treatment of hepatitis B and certain cancers. ZADAXIN currently is approved for sale in certain international locations, primarily in Asia, the Middle East and Latin America, and is marketed through the Company's wholly-owned subsidiary SciClone Pharmaceuticals International Ltd. ("SPIL"). SciClone's other proprietary drug development candidate is SCV-07, which is currently in pre-clinical studies for the treatment of viral and other infectious diseases.

Basis of Presentation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, SPIL, SciClone Italy S.R.L., SciClone Japan K.K., and SciClone do Brasil – Produtos Farmaceuticos Ltda. SPIL is registered in the Cayman Islands with its principal office located in Hong Kong. SciClone Italy S.R.L. is registered in Italy with its principal office located in Rome. SciClone Japan K.K. is registered in Japan with its principal office located in Tokyo. SciClone do Brasil is registered in Brazil with its principal office located in Sao Paulo. All significant intercompany accounts and transactions have been eliminated.

Revenue Recognition

The Company recognizes revenue from product sales at the time of shipment. There are no significant customer acceptance requirements or post shipment obligations on the part of the Company. Sales to importing agents or distributors are recognized at time of shipment when title to the product is transferred to them, and they do not have contractual rights of return except under limited terms regarding product quality. However, the Company will replace products that have expired or are deemed to be damaged or defective when delivered. Payments by the importing agents and distributors are not contingent upon sale to the end user by the importing agents or distributors.

Contract revenue for research and development is recorded as earned based on the performance requirements of the contract. Nonrefundable contract fees for which no further performance obligations exist, and there is no continuing involvement by the Company, are recognized on the earlier of when the payments are received or when collection is assured.

Revenue associated with substantive performance milestones is recognized based on the achievement of the milestones, as defined in the respective agreements and provided that (i) the milestone event is substantive and its achievement is not reasonably assured at the inception of the agreement, and (ii) there are no future performance obligations associated with the milestone payment.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Cash Equivalents and Investments

Cash equivalents consist of highly liquid investments with original maturities of three months or less.

The Company is required by its lease agreement to have a letter of credit secured by a certificate of deposit of $633,000 at December 31, 2004. Under its European value added tax filing arrangement, the Company has a letter of credit secured by a certificate of deposit of $67,000 at December 31, 2004. These amounts are recorded as restricted short-term investments on the accompanying balance sheets.

The Company classifies its entire investment portfolio as available-for-sale and records these investments at fair value, as determined by available market information, on the balance sheet. The portfolio primarily consists of U.S. Government securities and short-term municipals. Unrealized gains or losses are included in accumulated other comprehensive income on the consolidated balance sheet. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in investment income along with interest earned. Realized gains or losses are determined on the basis of specific identification and included in investment income. Management believes the credit risk associated with these investments is limited due to the nature of the investments.

For the years ended December 31, 2004, 2003 and 2002, net unrealized (loss) gains of approximately $(138,000), $97,000, and $40,000, respectively, were included in accumulated other comprehensive income. For the year ended December 31, 2004, a net realized gain of approximately $697,000 was recognized primarily in connection with the sale of equity securities, and for the years ended December 31, 2003 and 2002, net realized gains were less than $1,000 for both years.

Fair Value of Financial Instruments

The fair value of our cash equivalents and marketable securities is based on quoted market prices. The carrying amount of cash equivalents and marketable securities are equal to their respective fair values at December 31, 2004 and 2003.

Other financial instruments, including accounts receivable, accounts payable and accrued liabilities, are carried at cost, which the Company believes approximates fair value because of the short-term maturity of these instruments. The Company believes the reported value of its convertible debt of $5,600,000 at December 31, 2004 and 2003 approximates the fair value.

Inventories

Inventories are stated at the lower of cost (first-in, first-out basis) or market.

Property and Equipment

Property and equipment is stated at cost, less accumulated depreciation. Depreciation is recorded over the estimated useful lives of the respective assets (three to five years) on the straight-line basis. Leasehold improvements are amortized over the shorter of the estimated useful life or lease term on the straight-line basis.

Intangible Assets

Intangible assets with definite lives are amortized over their estimated useful lives and are reviewed for impairment when facts or circumstances suggest that the carrying value of these assets may not be recoverable. The Company's policy is to identify and record impairment losses on intangible product rights when events and circumstances indicate that the assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets. The Company to date has not identified any impairment losses on these assets. Although the Company has a history of operating and cash flow losses, the Company believes that there is no impairment to the intangible assets because ZADAXIN has been approved for sale in several countries, principally as a treatment for hepatitis B. Based on the Company's anticipated financial results for future ZADAXIN sales, it has been determined that the expected future cash flows exceed the carrying amount of the assets.

Foreign Currency Translation

The Company translates the assets and liabilities of its foreign subsidiaries stated in local functional currencies to U.S. dollars at the rates of exchange in effect at the end of the period. Revenues and expenses are translated using rates of exchange in effect during the period. Gains and losses from the translation of financial statements denominated in foreign currencies, if material, are included as a separate component of other comprehensive income (loss) in the statement of stockholders' equity. There have been no accumulated currency translation gains or losses included in any period presented.

The Company records foreign currency transactions at the exchange rate prevailing at the date of the transaction. Monetary assets and liabilities denominated in foreign currency are retranslated at the exchange rates in effect at the balance sheet date. All translation differences arising from foreign currency transactions are included in results of operations and have not been significant.

Research and Development Expenses

Research and development expenditures are charged to operations as incurred. Major components of research and development expenses consist of clinical development performed on the Company's behalf by institutions and contract research organizations, personnel costs, including salaries and benefits, preclinical work, pharmaceutical development, materials and supplies, third party research funding and overhead allocations consisting of various administrative and facilities related costs. SciClone's research and development activities are also separated into three main categories: research, clinical development and pharmaceutical development. Research costs typically consist of preclinical and toxicology work. Clinical development costs essentially include clinical trials. Pharmaceutical development costs consist of product formulation and chemical analysis.

ZADAXIN clinical trials are the largest and most significant effect on the Company's research and development expenses. Cost accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous institutions that conduct the clinical trials on the Company's behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients and the completion of portions of the clinical trial or similar conditions. The objective of the accrual policy is to match the recording of expenses to the actual services received and efforts expended. Expenses related to grants to institutions that conduct the clinical trials on the Company's behalf are accrued based on the level of patient enrollment and activity according to the protocol. In general, these expenses will be higher for the initial and final months of a patient's scheduled 18 months of treatment and observation. Expenses relating to the clinical research organization and other entities managing the trials and laboratory and other direct expenses are recognized in the period they are estimated to be incurred and the services performed. The Company monitors active patient enrollment levels and related activity to the extent possible and adjusts estimates accordingly.

Shipping and Handling Costs

Costs related to shipping and handling are included in cost of sales for all periods presented.

Advertising Expenses

The Company expenses advertising costs as incurred and these costs are included in sales and marketing expenses for all periods presented. Advertising expenses for the years ended December 31, 2004, 2003 and 2002 were $235,000, $255,000 and $108,000, respectively.

Income Taxes

Income taxes are accounted for under the liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis, and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that included the enactment date. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some or all of the deferred tax assets may not be realized.

Net Loss Per Share

Basic net loss per share has been computed using the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share equals basic net loss per share given the Company's history of net losses.

Had the Company been in a net income position, diluted earnings per share would have included the shares used in the computation of basic net loss per share as well as the effect of an additional 8,979,653, 7,906,758 and 8,436,262 shares in 2004, 2003 and 2002, respectively, related to convertible notes payable, outstanding options and warrants. The impact of these shares was not included in the calculation of diluted net loss per share as their effect was antidilutive.

Accounting for Stock-Based Compensation

The Company accounts for its stock option and employee stock purchase plans under the provisions of Accounting Principles Board Opinion 25 ("APB 25") and related Interpretations. Accordingly, the Company does not generally recognize compensation expense in accounting for its stock option and employee stock purchase plans for awards to employees and directors.

Pro forma information regarding net loss and net loss per share is required by Statement of Financial Accounting Standards No. 123 "Accounting for Stock-Based Compensation" ("SFAS 123") and has been determined as if the Company had accounted for its stock awards under the fair value method of that Statement. The fair value for the options was estimated at the date of grant using a Black-Scholes option pricing model. The following weighted-average assumptions used for the years ended December 31 are as follows:

	2004	2003	2002
Weighted-average fair value of stock options granted	$3.22	$4.10	$2.75
Risk-free interest rate	2.59%	2.00%	2.00%
Dividend yield	0.00%	0.00%	0.00%
Volatility factor of the expected market price of our common stock	87.36%	93.29	95.62%
Weighted-average expected life of option (years)	4.00	4.03	3.88
Weighted-average fair value of employee stock purchase plan purchases	$1.83	$1.74	$0.99
Risk-free interest rate	3.32%	2.00	2.00%
Dividend yield	0.00%	0.00%	0.00%
Volatility factor of the expected market price of our common stock	85.34%	94.31%	95.62%
Weighted-average expected life (years)	0.24	0.25	0.25

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because the Company's employee and director stock awards have characteristics significantly different from those of traded options, and because changes in subjective input assumptions can materially affect the fair value estimate, in the Company's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its stock options and stock purchases.

Had compensation expense for the Company's option and employee stock purchase plans been determined based on the fair value at the grant date for awards in 2004, 2003 and 2002 consistent with the provisions of SFAS 123, the Company's net loss and net loss per share would have been adjusted to the pro forma amounts for the years ended December 31 as indicated below:

	2004	2003	2002
Net loss—as reported	$ (13,278,000)	$ (5,275,000)	$ (10,037,000)
Total stock-based employee compensation expense determined under the fair value based method for all awards	(4,257,000)	(3,010,000)	(2,283,000)
Net loss—pro forma	$ (17,535,000)	$ (8,285,000)	$ (12,320,000)
Basic and diluted net loss per share—as reported	$ (0.30)	$ (0.13)	$ (0.29)
Basic and diluted net loss per share—pro forma	$ (0.39)	$ (0.21)	$ (0.35)

The effects of applying SFAS 123 for pro forma disclosures are not likely to be representative of the effects on reported net loss for future years due primarily to the different number of options granted each year.

Warrants issued in connection with equity and debt arrangements and equity instruments issued to non-employees are valued using the Black-Scholes option valuation model. Warrants issued to placement agents and similar parties in connection with equity financing are accounted for as stock issuance costs with an equal amount recorded as additional paid-in capital. Warrants issued to purchasers of the Company's equities are not separately included in the financial statements as their value is a sub-component of

additional paid-in capital. The fair value of warrants issued in connection with debt arrangements, if material, is accounted for as a debt discount and amortized as additional interest expense over the term of the related debt.

Comprehensive Income (Loss)

The Company reports changes in unrealized gains or losses on the Company's available-for-sale securities in comprehensive income (loss). The accumulated other comprehensive income balances represent the unrealized gains or losses on these securities at the balance sheet dates.

Segment Information

The Company operates in one segment (see Note 14).

Concentration of Credit Risk

The People's Republic of China, like Japan and certain other Asian markets, uses a tiered method to import and distribute products. The distributors make the sales in the country, but the product is imported for them by licensed importers. For the year ended December 31, 2004, sales to four importing agents in China accounted for 91% of the Company's product sales and sales to five importing agents in China accounted for 88% of the Company's product sales for the year ended December 31, 2003 and sales to six importing agents accounted for 88% of product sales for the year ended December 31, 2002. In 2004, the three largest customers accounted for 32%, 29% and 23% of sales, respectively. No other customer accounted for more than 10% of sales in 2004. In 2003, the largest customer accounted for 52% of sales and the second largest customer accounted for 14% of sales. No other customers accounted for more than 10% of sales in 2003. In 2002, the largest customer accounted for 41% of sales and the second largest customer accounted for 27% of sales. No other customers accounted for more than 10% of sales in 2002. In each of these three years, the same importing agent was the single largest customer. As of December 31, 2004, approximately $9,609,000, or 90% of the Company's accounts receivable were attributable to four importing agents in China. The Company performs on-going credit evaluations of its customers' financial condition, and generally does not require collateral from its customers. The Company maintains reserves for credit losses, and such losses have been within management's expectation. The Company recognizes reserves for bad debts ranging from 25% to 100% based on the length of time the receivables are past due and the Company's collectibility experience.

Recently Issued Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board ("FASB") issued FASB Statement No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123R") which revises SFAS 123, and supersedes APB 25, and its related implementation guidance. Generally the approach in SFAS 123R is similar to the approach described in SFAS 123. However, SFAS 123R requires share-based payments to employees and directors, including grants of stock options, to be recognized in the statement of operations based on their fair values. Pro forma disclosure is no longer an alternative. The amount of compensation cost will be measured based on the grant-date fair value of the instruments issued. Compensation cost will be recognized over the period that an employee or director provides service in exchange for the award. We expect to adopt SFAS 123R on July 1, 2005.

As permitted by SFAS 123, the Company currently accounts for share-based payments to employees and directors using APB 25's intrinsic value method and, as such, generally recognizes no compensation cost for employee and director stock options. Accordingly, the adoption of SFAS 123R's fair value method will have a significant impact on our result of operations, although it will have no impact on our overall financial position. The impact of adoption of SFAS 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had we adopted SFAS 123R in prior periods, the impact of that standard would have approximated the impact of SFAS 123 as described in the disclosure of pro forma net loss and net loss per share in the Accounting for Stock-Based Compensation section of Note 1 to our consolidated financial statements.

Note 2 — Available-for-sale Securities

The following is a summary of available-for-sale securities:

	Available-For Sale Securities		
	Amortized Cost	Gross Unrealized Gains	Estimated Fair Value
December 31, 2004:			
Certificates of deposit	$ 805,000	$ —	$ 805,000
U.S. government obligations	22,843,000	—	22,843,000
Short-term municipal securities	9,200,000	—	9,200,000
Corporate equity securities	51,000	38,000	89,000
	$ 32,899,000	$ 38,000	$ 32,937,000
December 31, 2003:			
Certificates of deposit	$ 798,000	$ —	$ 798,000
U.S. government obligations	38,259,000	—	38,259,000
Short-term municipal securities	9,050,000	—	9,050,000
Corporate equity securities	51,000	176,000	227,000
	$ 48,158,000	$176,000	$ 48,334,000

As of December 31, 2004, the total available-for-sale securities are included on the accompanying balance sheets as follows, $22,843,000 in cash and cash equivalents, $700,000 in restricted short-term investments and $9,395,000 in other short-term investments. As of December 31, 2003, the total available-for-sale securities are included as follows, $38,259,000 in cash and cash equivalents, $695,000 in restricted short-term investments and $9,381,000 in other short-term investments. As of December 31, 2004 and 2003 all available-for sale securities excluding the short-term municipal securities had maturities of 12 months or less. The short-term municipals are auction rate securities which have long final maturities, however, because they are highly rated, highly liquid and their interest rate is reset at auction every 30 days, they are included as available-for-sale securities. The Company's interest rate risk associated with these securities is limited due to this interest rate reset mechanism.

Note 3 — Prepaid Expenses and Other Current Assets

The following is a summary of prepaid expenses and other current assets:

	December 31,	
	2004	2003
Prepaid insurance	$ 694,000	$ 717,000
Prepaid rent	102,000	100,000
Prepaid clinical trial expense	247,000	1,085,000
VAT receivable	142,000	208,000
Other prepaid expenses	293,000	346,000
	$ 1,478,000	$ 2,456,000

Note 4 — Inventories

Inventories consisted of the following:

	December 31,	
	2004	2003
Raw materials	$ 1,517,000	$ 1,577,000
Work in progress	276,000	1,955,000
Finished goods	2,386,000	2,246,000
	$ 4,179,000	$ 5,778,000

Note 5 — Property and Equipment

Property and equipment consisted of the following:

	December 31, 2004	December 31, 2003
Office furniture and fixtures	$ 290,000	$ 243,000
Office equipment	788,000	667,000
Leasehold improvements	139,000	121,000
	1,217,000	1,031,000
Less accumulated depreciation and amortization	(819,000)	(706,000)
Net property and equipment	$ 398,000	$ 325,000

Depreciation expense for the years ended December 31, 2004, 2003 and 2002 was $115,000, $90,000 and $122,000, respectively.

Note 6 — Intangible Assets

Intangible assets include the following:

	December 31, 2004	December 31, 2003
Intangible product rights	$ 2,456,000	$ 2,456,000
Accumulated amortization	(1,914,000)	(1,844,000)
	$ 542,000	$ 612,000

In December 1997 the Company entered into an agreement with Alpha 1 Biomedicals, Inc. ("A1B") to acquire the worldwide rights, except in Italy, Spain and Portugal, where Sclavo S.p.A. ("Sclavo"), an international pharmaceutical entity, owned exclusive marketing rights, to ZADAXIN, which rights A1B had licensed from Hoffmann-LaRoche, Inc. and F. Hoffmann-LaRoche AG, for approximately $1,800,000. The transaction closed in July 1998 and eliminated the Company's royalty obligation to A1B with respect to all sales of ZADAXIN after the acquisition date. In April 1998, the Company entered into an agreement with Sclavo to acquire ZADAXIN rights for Italy, Spain and Portugal from Sclavo for approximately $1,400,000.

In connection with the foregoing transactions with Sclavo and A1B, the Company estimated the fair market value of the intangible assets purchased to be approximately $2,456,000 and wrote off the remaining $700,000 related to hepatitis C in-process technology.

Acquired ZADAXIN product rights are being amortized on a straight-line basis over their estimated useful lives. Amortization expense for the year ended December 31, 2002 was $409,000 based on an estimated useful life of six years. Amortization expense for the years ended December 31, 2004 and 2003 was $70,000 per year and for the years 2005 through 2012 is expected to be $70,000 per year. The Company has reassessed the estimated useful life of the assets as of January 1, 2003 to be an additional eight years through 2012. Based upon the progress in the ZADAXIN clinical trials and the Company’s actual experience of product sales, the Company assessed that the acquired product rights will be useful to the Company through 2012 when the European patent for the use of ZADAXIN in the treatment of hepatitis C expires. The Company reassesses the useful life of these assets in accordance with current facts and circumstances.

Note 7 — Other Accrued Expenses

The following is a summary of other accrued expenses:

	December 31, 2004	December 31, 2003
Accrued royalties	$ 420,000	$ 323,000
Accrued annual reports/website expenses	81,000	120,000
Accrued pre-clinical trial expenses	133,000	—
Accrued interest payable	52,000	52,000
Other	231,000	136,000
	$ 917,000	$ 631,000

Note 8 — Collaborative Agreements

In May 2004, the Company entered into an agreement with Sigma-Tau, whereas Sigma-Tau will be conducting a multi-center phase 3 hepatitis C triple therapy clinical trial in Europe with approximately 550 patients. The objective of the European trial is to provide data on ZADAXIN's use as part of a triple therapy in treating HCV patients. The Company will provide ZADAXIN, and approximately $2,500,000 of funding support and a $1,500,000 milestone payment to Sigma-Tau at the completion of the study.

In October 2003, the Company and Wayne State University ("WSU") amended a license agreement that WSU and A1B had entered into in 1994 that was subsequently assigned by A1B to SciClone. The 2003 amendment allows the Company to maintain an exclusive license to certain WSU patents regarding the use of thymosin alpha 1 in the treatment of hepatitis B and hepatitis C. In addition to certain minimum royalty payments following sales of ZADAXIN in certain territories, the Company is obligated to pay WSU a total of $1,400,000 in pre-paid royalties over the following three years whether or not the Company receives regulatory approval for ZADAXIN or sales are made in the covered territories including the United States. The Company can offset the annual minimum royalties due on sales of ZADAXIN with these pre-paid royalties to the extent of 50% of the annual royalties in any one year. In the year ended December 31, 2004 and 2003, the Company paid $300,000 and $200,000, respectively of the pre-paid royalties. These amounts plus the unpaid balance of $900,000 that is due over the next two years have been recorded as pre-paid royalties in the long term other assets account on the accompanying balance sheets. The remaining obligation to pay $900,000 has been included in other accrued expenses and other long term liabilities on the accompanying balance sheets.

In April 1999, the Company licensed to Sigma-Tau semi-exclusive ZADAXIN development and marketing rights in Italy and Spain, and exclusive rights in Switzerland. In March 2000, this license was expanded and amended to include all of the countries then in the European Union and Sigma-Tau was made exclusive licensee in these countries. In December 2001, this license was further amended to define the scope of clinical development for ZADAXIN that Sigma-Tau would undertake in Europe. Under the terms of the December 2001 amendment, the Company received $2,685,000 in the first quarter of 2002. This contract revenue is being recognized over the estimated time to complete the ZADAXIN U.S. phase 3 HCV clinical trials and deliver the clinical data, the substantive performance requirements under the contract amendment. For the year ended December 31, 2004, 2003 and 2002, the Company recognized $537,000, $806,000 and $671,000, respectively, as contract revenue and the remaining $671,000 is recorded as deferred revenue as of December 31, 2004. Additionally, in the second quarter of 2004, the Company recognized a $1,000,000 milestone payment from Sigma-Tau for the full enrollment of the Company's current phase 3 U.S. clinical trials as there are no future performance obligations associated with the milestone payment.

In August 1997 the Company entered into a ZADAXIN Patent License Agreement with The Fitzsimons Army Medical Center of the U.S. Army (the "U.S. Army"). The Company is obligated to pay the U.S. Army a minimum annual royalty and a royalty based on a percentage of ZADAXIN net sales revenue upon commercialization of ZADAXIN for treatment of chronic hepatitis C in certain countries, including the U.S., the European Union and Japan, but not including China.

Note 9 — Other Long-term Liabilities

The following is a summary of other long-term liabilities:

	December 31,	
	2004	2003
Accrued compensation and employee benefits	$ 544,000	—
Accrued royalties	500,000	900,000
	$ 1,044,000	$ 900,000

Note 10 — Income Taxes

The domestic and foreign components of pre tax income (loss) for the years ended December 31 are as follows:

	2004	2003	2002
Domestic	$ (17,433,000)	$ (15,768,000)	$ (9,510,000)
Foreign	4,155,000	10,493,000	(527,000)
Loss	$ (13,278,000)	$ (5,275,000)	$ (10,037,000)

Significant components of the Company's deferred tax assets at December 31 are as follows:

	2004	2003
Assets		
Net operating loss carryforwards	$ 36,264,000	$ 30,212,000
R&D credit carryforwards	5,474,000	5,238,000
Other	1,156,000	1,095,000
Gross deferred tax assets	42,894,000	36,545,000
Valuation allowance	(42,894,000)	(36,545,000)
Total deferred tax assets	$ —	$ —

The valuation allowance increased by approximately $6,349,000, $5,825,000 and $3,272,000 in the years ended December 31, 2004, 2003 and 2002, respectively. Deferred tax assets relating to carryforwards as of December 31, 2004 include approximately $7,504,000 associated with stock option activity for which any subsequently recognized tax benefits will be credited directly to stockholders' equity. The Company did not have any deferred tax liabilities at December 31, 2004 or 2003.

At December 31, 2004, the Company has net operating loss carryforwards for federal income tax purposes of approximately $104,000,000 which expire in the years 2006 through 2024. At December 31, 2003, the Company has federal tax credit carryforwards of approximately $5,000,000 which expire in the years 2006 through 2024.

At December 31, 2004, the Company has state net operating loss carryforwards of approximately $17,000,000 available to reduce future taxable income. The carryforwards begin to expire in 2005, if not utilized. In addition, the Company has research and development tax credit carryforwards of approximately $700,000 for state tax purposes at December 31, 2004. The tax credit carryforward will be carried forward indefinitely until utilized.

Because of the "change in ownership" provisions of the Internal Revenue Code, a portion of the Company's net operating loss carryforwards and tax credit carryforwards may be subject to an annual limitation regarding their utilization against taxable income in future periods. As a result of the annual limitation, a portion of these carryforwards may expire before ultimately becoming available to reduce future income tax liabilities.

As a result of net losses, the Company did not record any state income tax expense for the years ended December 31, 2004, 2003 and 2002.

Note 11 — Commitments and Contingencies

Leases

The Company leases its main office facility under a non-cancelable operating lease agreement which expires in August 2007. The lease is for a period of seven years and requires the Company to pay insurance and taxes and its pro-rata share of operating expenses. The Company also leases various office facilities abroad under non-cancelable lease agreements, expiring in 2005. Rent expense in 2004, 2003 and 2002 was $1,393,000, $1,362,000 and $1,376,000, respectively. Minimum future rental payments amount to a total of $3,540,000, which consists of $1,378,000 in 2005, $1,299,000 in 2006 and $863,000 in 2007.

Royalties

Under the October 2003 amendment to the Patent License Agreement with Wayne State University, the Company is obligated to pay WSU a royalty, subject to minimum amounts, on a percentage of ZADAXIN net sales revenue for the treatment of hepatitis B and

hepatitis C in certain countries including the United States, the European Union and Japan, but not including China. In addition, the Company is obligated to pay WSU pre-paid royalties of $400,000 and $500,000 in 2005 and 2006, respectively, whether or not the Company receives regulatory approval for ZADAXIN or sales are made in the covered territories including the United States. The Company can offset the annual minimum royalties due on sales of ZADAXIN with these pre-paid royalties to the extent of 50% of the annual royalties in any one year. In the year ended December 31, 2004 and 2003, the Company paid WSU $300,000 and $200,000, respectively, of pre-paid royalties.

Under the August 1997 ZADAXIN Patent License Agreement with the U.S. Army, the Company is obligated to pay the U.S. Army a minimum annual royalty and a royalty based on a percentage of ZADAXIN net sales revenue upon commercialization of ZADAXIN for treatment of chronic hepatitis C in certain countries including the U.S., the European Union and Japan, but not including China. During 2004, 2003 and 2002 the Company paid $20,000 per year to the U.S. Army related to the minimum annual royalty.

Convertible Notes Payable

In March 2001, the Company issued a $1,600,000 convertible note to an investment affiliate of UBS AG. The $1,600,000 note is convertible into 276,530 shares of common stock at a fixed conversion price of $5.7860 per share. The note accrues interest at a rate of 6% per year payable semi-annually and will mature in March 2006. The Company also received $354,000 for granting the investor the right to purchase, at any time up to the note's maturity date, approximately $2,400,000 of convertible notes due March 2006. If issued, the notes will bear no interest (zero coupon) and will be convertible into 276,530 shares of common stock at a fixed conversion price of $8.5532 per share. The Company may elect in lieu of delivering convertible notes to deliver the respective number of shares of common stock.

In December 2000, the Company issued a $4,000,000 convertible note to an investment affiliate of UBS AG. The $4,000,000 note is convertible into 407,610 shares of common stock at a fixed conversion price of $9.8133 per share. The note will accrue interest at a rate of 6% per year payable semi-annually and will mature in December 2005. The Company also received $900,000 for granting the investor the right to purchase, at any time up to the note's maturity date, approximately $5,900,000 of convertible notes due December 2005. If issued, the notes will bear no interest (zero coupon) and will be convertible into 407,610 shares of common stock at a fixed conversion price of $14.5066 per share. The Company may elect in lieu of delivering convertible notes to deliver the respective number of shares of common stock.

Note 12 — Stockholders' Equity

On July 18, 2003, the Company reincorporated from a California corporation to a Delaware corporation by merging the Company, then a California corporation, with and into SciClone Pharmaceuticals Inc., a Delaware corporation and wholly-owned subsidiary of the Company. Each share of outstanding stock of the California corporation was automatically exchanged for a like share of stock of the Delaware corporation.

Common Stock and Warrants

In July 2004 when the former CEO left the Company, his outstanding unvested options to purchase 253,541 shares of the Company's common stock became fully vested and all of his outstanding options to purchase 1,615,454 shares became exercisable for a one or two year period. These changes to the former CEO's options did not result in any stock-based compensation as the changes were effected in accordance with the original terms of the option grants.

In September 2003, the Company completed a public offering of 6,000,000 shares of common stock at $8.00 per share and received proceeds of $45,120,000 from the sale, net of $694,000 of financing-related costs.

In January 2003, the Company completed a $1,800,000 direct placement to affiliates of Sigma-Tau. The affiliates purchased 504,938 shares of the Company's common stock at $3.5648 per share. The shares issued were restricted securities, and Sigma-Tau and its affiliates were not permitted to sell any of the shares purchased in this private placement until January 24, 2004.

In June 2002, the Company completed a direct offering of common stock to institutional investors. The Company raised net proceeds of $9,914,000 from the offering of 4,088,460 shares of common stock at $2.60 per share.

In January 2000, the Company completed a $6,100,000 private placement to Brown Simpson Asset Management which purchased 1,000,000 shares of common stock at a price of $6.00 per share and five-year immediately exercisable warrants to purchase 800,000 shares of common stock at an exercise price of $7.00 per share. As of December 31, 2004, none of these warrants had been exercised and the exercise period of all these warrants expired in January 2005. In addition, the placement agent for this transaction received, as part of its fee, five-year warrants to purchase 108,000 shares of common stock at an exercise price of $7.00 per share. In 2003, warrants to purchase 3,240 shares of common stock were exercised for proceeds of $22,680. As of December 31, 2004, placement agent warrants to purchase 104,760 of common stock had not been exercised and the exercise period of all of these warrants expired in January 2005.

In January 1999, the Company issued warrants to purchase a total of 150,000 shares of common stock to Cato Research Ltd. as part of a settlement agreement. Of this total, warrants to purchase 50,000 shares of common stock were exercised at a price of $1.225 for proceeds of $61,250 in March 2000. In January 2004, the remaining warrants to purchase 100,000 shares of common stock were exercised at a price of $2.25 for 65,753 shares of common stock.

Stock Award Plans

In August 1991, the Board of Directors and stockholders of the Company approved the 1991 Stock Plan (the "1991 Plan") and reserved 1,300,000 shares for issuance thereunder. In May 1993, the Board of Directors and stockholders of the Company approved a 2,150,000 increase in the shares reserved under the 1991 Plan. The 1991 Plan permits the award of incentive or nonqualified stock options and shares of common stock under restricted stock purchase agreements. In January 1992, the Board of Directors and stockholders of the Company approved the 1992 Stock Plan (the "1992 Plan") and reserved 240,000 shares for issuance thereunder. The 1992 Plan permits the award of incentive or nonqualified stock options which must be exercised in cash. In June 1995, the Board of Directors and the stockholders of the Company approved the 1995 Equity Incentive Plan (the "1995 Plan") and reserved 1,250,000 shares for issuance thereunder. The 1995 Plan permits the award of incentive or nonqualified stock options and shares of common stock under restricted stock awards. In May 1997, the Board of Directors and stockholders of the Company approved a 750,000 increase in the shares reserved under the 1995 Plan. In June 1998, June 2000 and June 2002 the Board of Directors and stockholders of the Company approved increases of 1,500,000, 1,250,000 and 1,350,000, respectively, in the shares reserved under the 1995 Plan. Although the 1995 Plan expired on January 1, 2005, the outstanding options relating to it are fully valid. In May 2004, the Board of Directors and the stockholders of the Company approved the 2004 Stock Option Plan (the “2004 Plan”) and reserved 2,500,000 shares for issuance thereunder. The 2004 Plan permits the award of incentive stock options or nonstatutory stock options.

Under the 1991, 1992, 1995 and 2004 Plans, options are exercisable upon conditions determined by the Board of Directors and expire ten years from the date of grant. Options are generally granted at fair market value on the date of grant and vest over time, generally four years.

In June 1995, the Board of Directors and the stockholders of the Company approved the Nonemployee Director Stock Option Plan (the "Nonemployee Director Plan") and reserved 250,000 shares for issuance thereunder. In June 2000 and June 2002 the Board of Directors and stockholders of the Company approved 250,000 increases in the shares reserved for issuance under the Nonemployee Director Plan. In May 2004, the Board of Directors and stockholders of the Company approved the 2004 Outside Directors Stock Option Plan and reserved 465,000 shares for issuance thereunder and the Nonemployee Director Stock Option Plan was canceled. The 2004 Outside Directors Stock Option Plan automatically grants nonqualified stock options to nonemployee directors upon their appointment or first election to the Company’s Board of Directors (“Initial Grant”) and annually upon their reelection to the Board of Directors at the Company’s Annual Meeting of Stockholders (“Annual Grant”). The options are granted at fair market value on the date of grant. Initial grants will become exercisable in three equal annual installments beginning on the first anniversary of the date of grant, and Annual grants will become exercisable in twelve equal monthly installments from the date of grant, subject in each case to the Outside Director’s continuous service on our Board of Directors.

The following table summarizes the stock option activity under the 1991, 1992, 1995 and 2004 Stock Option Plans, the Nonemployee Director Plan and the 2004 Outside Director Stock Option Plan:

		Options Outstanding	
	Shares Available For Grant	Number of Shares	Weighted Average Exercise Price
Balance at December 31, 2001	1,025,869	4,926,857	4.86
1995 Plan shares reserved	1,350,000	—	—
Nonemployee Director Plan shares reserved	250,000	—	—
Options canceled	349,979	(349,979)	6.67
Options granted	(795,500)	795,500	4.13
Options exercised	—	(274,896)	1.87
Plan shares expired	(126,542)	—	—
Balance at December 31, 2002	2,053,806	5,097,482	4.76
Options canceled	345,168	(345,168)	7.43
Options granted	(1,162,034)	1,162,034	6.17
Options exercised	—	(380,630)	2.76
Plan shares expired	(79,697)	—	—
Balance at December 31, 2003	1,157,243	5,533,718	5.02
2004 Plan shares reserved	2,500,000	—	—
2004 Outside Directors Plan shares reserved	465,000	—	—
Options canceled	225,955	(225,955)	6.35
Options granted	(1,402,000)	1,402,000	5.05
Options exercised	—	(3,150)	3.79
Plan shares expired	(269,775)	—	—
Balance at December 31, 2004	2,676,423	6,706,613	4.99

The following table summarizes information concerning outstanding and exercisable options as of December 31, 2004:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$1.22 - $2.47	1,214,391	4.09	$ 1.68	1,214,391	$ 1.68
$2.67 - $4.25	1,546,416	6.93	3.89	1,214,126	3.87
$4.50 - $5.23	1,148,267	7.34	4.92	472,250	4.85
$5.25 - $5.83	1,801,614	5.84	5.63	1,097,008	5.56
$5.88 - $10.75	990,925	4.80	9.62	969,029	9.68
$12.50	5,000	5.16	12.50	5,000	12.50
	6,706,613	5.88	4.99	4,971,804	4.94

As of December 31, 2003 and 2002, options outstanding were exercisable for 3,943,906 and 3,677,142 shares, respectively.

In July 1996, the Board of Directors and stockholders of the Company approved the 1996 Employee Stock Purchase Plan (the "ESPP") and reserved 500,000 shares for issuance thereunder. In June 2003, the Board of Directors and stockholders of the Company approved 500,000 increases in the shares reserved for issuance under the 1996 Employee Stock Purchase Plan. All full-time employees are eligible to participate in the ESPP. Under the terms of the ESPP, employees can choose to have up to 15% of their salary withheld to purchase the Company's common stock. The purchase price of the stock is 85% of the lower of the fair market value as of the first and last trading day of each quarterly participation period. Under the ESPP, the Company sold 124,798, 127,920 and 67,160 shares to employees in 2004, 2003 and 2002, respectively.

Reserved Shares

As of December 31, 2004, the Company had reserved shares of common stock for future issuance as follows:

Options outstanding	6,706,613
Shares available for grant....	2,676,423
Warrants outstanding	904,760
Convertible notes payable...	1,368,280
ESPP	385,086
	12,041,162

Note 13 — 401k Plan

The Company has a pre-tax savings plan covering substantially all U.S. employees, which qualifies under Section 401(k) of the Internal Revenue Code. Under the plan, eligible employees may contribute a portion of their pre-tax salary, subject to certain limitations. The Company contributes and matches 50% of the employee contributions, up to 15% of an employee's salary. Company contributions, which can be terminated at the Company's discretion, were approximately $161,000, $129,000 and $101,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

Note 14 — Significant Geographic Information

The Company operates in one business segment, the development and commercialization of specialist-oriented proprietary drugs for the treatment of chronic and life threatening diseases. Currently, the Company's principal focus has been the development and commercialization of ZADAXIN, the only product that the Company sells.

The Office of the President, consisting of the Chief Operating Officer and Chief Financial Officer, has been identified as the Chief Operating Decision Makers ("CODM") because they have final authority over resource allocation decisions and performance assessment. The CODM does not receive discrete financial information about the individual components of the business segment.

The Company's domestic operations primarily consist of product development. The Company's wholly owned international subsidiary, SciClone Pharmaceuticals International Ltd., is engaged in sales and marketing and product distribution worldwide.

Information regarding geographic areas is as follows:

	Product Sales for the Year Ended December 31,	Contract Revenue for the Year Ended December 31,	Long Lived Assets December 31,	Net Assets December 31,
2004:				
U.S.....	$ —	$ —	$ 1,980,000	$ 26,892,000
China	20,714,000	—	283,000	28,014,000
Other.....	2,051,000	1,631,000	211,000	217,000
Total ...	$ 22,765,000	$ 1,631,000	$ 2,474,000	$ 55,123,000
2003:				
U.S.....	$ —	$ —	$ 2,043,000	$ 45,093,000
China	28,078,000	—	213,000	22,928,000
Other.....	3,654,000	806,000	215,000	229,000
Total ...	$ 31,732,000	$ 806,000	$ 2,471,000	$ 68,250,000
2002:				
U.S.....	$ —	$ —	$ 624,000	$ 9,417,000
China	15,073,000	—	99,000	13,728,000
Other.....	2,028,000	671,000	234,000	209,000
Total ...	$ 17,101,000	$ 671,000	$ 957,000	$ 23,354,000

Three customers accounted for 10% or more of total revenues (32%, 29% and 23%) for an aggregate of 84% of total revenues for the year ended December 31, 2004. Two customers accounted for 10% or more of total revenues (52% and 14%) for an aggregate of

66% of total revenues for the year ended December 31, 2003. Two customers accounted for 10% or more of total revenues (41% and 27%) for an aggregate of 68% of total revenues for the year ended December 31, 2002. No other customer accounted for more than 10% of total revenues during these years.

Note 15 — Selected Quarterly Financial Data (unaudited)

	Three Months Ended			
	March 31	June 30	September 30	December 31
2004:				
Product sales	$ 5,414,000	$ 5,613,000	$ 5,753,000	$ 5,985,000
Contract revenue	228,000	1,135,000	134,000	134,000
Cost of product sales	1,142,000	1,178,000	1,109,000	1,148,000
Gross margin	4,500,000	5,570,000	4,778,000	4,971,000
Net loss	(3,133,000)	(2,877,000)	(4,913,000)	(2,355,000)
Basic net loss per share	(0.07)	(0.06)	(0.11)	(0.05)
Diluted net loss per share	(0.07)	(0.06)	(0.11)	(0.05)
2003:				
Product sales	$ 5,000,000	$ 16,207,000	$ 5,421,000	$ 5,104,000
Contract revenue	224,000	224,000	224,000	134,000
Cost of product sales	1,016,000	2,931,000	935,000	754,000
Gross margin	4,208,000	13,500,000	4,710,000	4,484,000
Net income (loss)	(2,862,000)	5,124,000	(2,850,000)	(4,687,000)
Basic net income (loss) per share	(0.08)	0.14	(0.07)	(0.11)
Diluted net income (loss) per share	(0.08)	0.13	(0.07)	(0.11)

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

Not applicable

Item 9A. ***Controls and Procedures***

(a) Evaluation of Disclosure Controls and Procedures

Disclosure Controls and Procedures

As of the end of the period covered by this report, the Company carried out an evaluation, under the supervision and with the participation of its management, including the two members of the Office of the President, who are our Chief Financial Officer and Chief Operating Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures in ensuring that material information required to be disclosed in the Company's reports filed or submitted under the Exchange Act has been made known to them in a timely fashion.

Management's Report on Internal Control over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. The Company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. All control systems have inherent limitations so that no evaluation of controls can provide absolute assurance that all control issues are detected. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our Office of the President, we assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2004, based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control-Integrated Framework. Based on this assessment and those criteria, management believes that the Company maintained effective internal control over financial reporting as of December 31, 2004.

Ernst & Young LLP, an independent registered public accounting firm, has audited management's assessment of the effectiveness of the Company's internal control over financial reporting as of December 31, 2004, as stated in their report which is included elsewhere herein.

Changes in Internal Control over Financial Reporting

There was no change in the Company's internal control over financial reporting identified in connection with the evaluation that occurred during the fourth quarter of 2004 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. There has been no change in internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. ***Other Information***

Not applicable

PART III

Item 10. ***Directors and Executive Officers of the Registrant***

The information required by Item 401 of Regulation S-K is incorporated by reference from the definitive proxy statement for the Company's 2005 Annual Meeting of Stockholders to be filed with the Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form (the "Proxy Statement") under the caption "ELECTION OF DIRECTORS — Nominees," and "ELECTION OF DIRECTORS — Board Meetings and Committees – *Audit Committee.*" Information relating to the executive officers of the Company is set forth in Part I of this Report under the caption "Executive Officers of the Registrant."

The information required by Item 405 of Regulation S-K is incorporated by reference from the Proxy Statement under the caption "EXECUTIVE COMPENSATION AND OTHER MATTERS — Section 16(a) Beneficial Ownership Reporting Compliance."

The information required by Item 406 of Regulation S-K, including the Code of Conduct, is posted on the Company's website at www.sciclone.com under corporate governance in the investor relations section.

Item 11. ***Executive Compensation***

The information required by this Item is incorporated by reference from the Proxy Statement under the captions "EXECUTIVE COMPENSATION AND OTHER MATTERS" and "ELECTION OF DIRECTORS — Compensation of Directors."

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

Equity Compensation Plan Information

As of December 31, 2004, the Company maintained seven compensation plans that provide for the issuance of common stock to officers and other employees, directors and consultants. These consist of the 1991 Stock Plan, the 1992 Stock Plan, the 1995 Equity Incentive Plan, the Nonemployee Director Stock Option Plan, the 1996 Employee Stock Purchase Plan, the 2004 Stock Option Plan and the 2004 Outside Directors Stock Option Plan, which plans have all been approved by the Company's stockholders. The Company does not currently maintain any compensation plans that have not been approved by the Company's stockholders. The following table sets forth information regarding outstanding options and shares reserved for future issuance under the foregoing plans as of December 31, 2004:

Plan Category	Number of shares to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of shares remaining available for future issuance under equity compensation plans (excluding shares reflected in column (a)) (c)
Equity compensation plans approved by stockholders:			
1991 Stock Plan	1,257,070	$4.6982	—
1992 Stock Plan	81,500	$5.3126	—
1995 Equity Incentive Plan	4,479,543	$4.8650	22,423
1995 Nonemployee Director Stock Option Plan	577,500	$6.6239	—
1996 Employee Stock Purchase Plan	0	0	385,086[(1)]
2004 Stock Option Plan	81,000	$3.8586	2,419,000
2004 Outside Directors Stock Option Plan	230,000	$5.0822	235,000
Total	6,706,613	$4.9859	3,061,509

(1) 1996 Employee Stock Purchase Plan is a voluntary plan open to all employees. This plan allows employees to elect payroll deductions which are used to purchase SciClone's common stock directly from the Company.

The information required by Item 403 of Regulation S-K is incorporated by reference from the Proxy Statement under the caption "STOCK OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT."

Item 13. ***Certain Relationships and Related Transactions***

The information required by this Item is incorporated by reference from the Proxy Statement under the caption "EXECUTIVE COMPENSATION AND OTHER MATTERS — Certain Relationships and Related Transactions."

Item 14. ***Principal Accountant Fees and Services***

The information required by this Item is incorporated by reference from the Proxy Statement under the caption "RATIFICATION OF APPOINTMENT OF INDEPENDENT AUDITORS – Principal Accountant Fees."

PART IV

Item 15. ***Exhibit, Financial Statement Schedules***

Item 15 (a). The following documents are filed as part of this Report:

(1) *Financial Statements.* The following financial statements of the Company are contained on pages 37 - 56 of this Report on Form 10-K:

Reports of Independent Registered Public Accounting Firm.

Consolidated Balance Sheets at December 31, 2004 and 2003.

Consolidated Statements of Operations for each of the three years in the period ended December 31, 2004.

Consolidated Statement of Stockholders' Equity for the three years ended December 31, 2004.

Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2004.

Notes to Consolidated Financial Statements.

(2) *Financial Statement Schedules*

The following schedule required to be filed by Item 8 of this form and Item 15(d) is contained on page 64 of this Report:

Schedule II — Valuation and Qualifying Accounts for each of the three years in the period ended December 31, 2004.

All other schedules have been omitted because they are either inapplicable or the required information has been given in the consolidated financial statements or the notes thereto.

(3) *Exhibits.*

Refer to Item 15(b) below.

Item 15 (b). **Exhibits.**

Exhibits (numbered in accordance with Item 601 of Regulation S-K):

Exhibit Number	Description
3(i).1(1)	Amended and Restated Certificate of Incorporation.
3(ii).1(1)	Bylaws.
4.1(9)	Rights Agreement dated as of July 25, 1997 between the Registrant and Chase Mellon Shareholder Services, LLC
4.2(1)	First Amendment to Rights Agreement dated as of July 17, 2003 between the Registrant and Mellon Investor Services LLC.
4.3(13)*	6% Convertible Note dated as of December 7, 2000 by the Registrant in favor of UBS AG, London Branch.
4.4(13)*	Option Agreement dated as of October 26, 2000 by and between the Registrant and UBS AG, London Branch.
4.5(13)*	Amendment No. 1 to Option Agreement dated as of December 19, 2000 by and between the Registrant and UBS AG, London Branch.
4.6(14)*	6% Convertible Note dated as of March 21, 2001 by the Company in favor of UBS AG, London Branch.
4.7(14)*	Option Agreement dated as of February 16, 2001 by and between the Company and UBS AG, London Branch.
4.8(14)*	Amendment No. 1 to Option Agreement dated as of March 21, 2001 by and between the Company and UBS AG, London Branch.
10.1(3)**	Registrant's 1991 Stock Plan, together with forms of agreements thereunder.
10.2(2)**	Registrant's 1992 Stock Plan, together with forms of agreements thereunder.
10.3(5)**	Registrant's 1995 Equity Incentive Plan, together with forms of agreement thereunder.
10.4(5)**	Registrant's 1995 Nonemployee Director Stock Option Plan, together with forms of agreement thereunder.
10.5(17)**	Registrant's 1996 Employee Stock Purchase Plan, as amended.
10.6(20)	Registrant's 2004 Stock Option Plan
10.7(20)	Registrant's 2004 Outside Directors Stock Option Plan
10.8(2)	Lease, dated September 10, 1991, between the Registrant and Spieker-Singleton68 concerning property, located at 901 Mariners Island Boulevard, San Mateo, California, as amended (the "Spieker Lease").
10.9(4)	Amendment No. 4 to Spieker Lease, dated October 4, 1994.
10.10(6)	Amendment No. 7 to Spieker Lease, dated November 14, 1995.
10.11(8)	Amendment No. 8 to Spieker Lease, dated August 26, 1996.
10.12(13)	Amendment No. 14 to Spieker Lease dated November 21, 2000.
10.13(19)	Employment Agreement, effective as of February 1, 1996, between the Registrant and Donald R. Sellers.
10.14(19)	Fifth Amendment of Employment Agreement, effective as of November 30, 2003, between the Registrant and Donald R. Sellers.
10.15(13)	Change in Control Agreement between the Company and Alfred Rudolph dated as of November 19, 1999.
10.16(13)	Change in Control Agreement between the Company and Donald R. Sellers dated as of November 19, 1999.
10.17(15)	Change in Control Agreement between the Company and Richard A. Waldron dated as of April 30, 2001.
10.18(17)	Change in Control Agreement between the Company and Hans P. Schmid dated as of April 22, 2003.
10.19(18)	Form of Indemnity Agreement by and between the Registrant and each director and executive officer of SciClone Pharmaceuticals, Inc.
10.20(21)*	Agreement Regarding Consulting, Resignation and General Release of Claims between Registrant and Donald R. Sellers, dated July 14, 2004.
10.21(7)*	License Agreement effective April 19, 1996 between the Registrant and the National Institute of Health Office of Technology Transfer.
10.22(10)	Alpha Rights Acquisition Agreement by and between the Registrant and Alpha 1 Biomedicals, Inc., dated December 17, 1997.
10.23(11)*	Expanded and Amended Thymosin Alpha 1 License, Distributorship and Supply Agreement by and between the

Exhibit Number	Description
	Company and Sigma-Tau Industrie Farmadeutiche Riunite S.p.A. dated as of March 3, 2000.
10.24(16)*	Amendment No. 1 to the Expanded and Amended Thymosin Alpha 1 License, Distributorship and Supply Agreement by and between the Company and Sigma-Tau Farmadeutiche Riunite S.p.A. dated as of December 19, 2001.
10.25(20)*	Amendment No. 2 to the Expanded and Amended Thymosin Alpha 1 License, Distributorship and Supply Agreement between the Registrant and Sigma-Tau Industrie Farmacetiche Riunite S.p.A., dated May 20, 2004.
10.26(20)*	Amendment No. 3 to the Expanded and Amended Thymosin Alpha 1 License, Distributorship and Supply Agreement between the Registrant and Sigma-Tau Industrie Farmacetiche Riunite S.p.A., dated May 21, 2004.
10.27(12)	Acquisition Agreement between the Company and Sclavo S.p.A. dated April 20, 1998.
10.28(12)	First Amendment to Acquisition Agreement between the Company and Sclavo S.p.A., dated April 20, 1998.
10.29(14)*	Registration Rights Agreement by and between the Company and UBS AG, London Branch dated as of February 16, 2001.
10.30(16)*	Common Stock Purchase Agreement between the Company and each of Defiante Farmaceutica Ld.A. and Aptafin S.p.A. dated as of January 21, 2003.
10.31(19)*	Manufacturing and Supply Agreement between SciClone Pharmaceuticals International Ltd. and Patheon Italia S.p.A. dated as of November 1, 2002.
10.32 (22)	Agreement between the Company and Alfred R. Rudolph, dated September 10, 2004.
10.33 (22)	Agreement between the Company and Richard A. Waldron, dated September 10, 2004.
21.1	Subsidiaries of Registrant.
23.1(23)	Consent of Independent Registered Public Accounting Firm.
24.1(23)	Powers of Attorney. See page 63.
31.1(23)	Rule 13a-14(a) Certification of member, Office of the President.
31.2(23)	Rule 13a-14(a) Certification of Chief Financial Officer and member, Office of the President.
32.1(23)	Section 1350 Certification of member, Office of the President.
32.2(23)	Section 1350 Certification of Chief Financial Officer and member, Office of the President.

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* Certain information in this exhibit has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request under 17 C.F.R. Sections 200.80(b)(4), 200.83 and 230.46.

** Management compensatory plan or arrangement.

(1) Incorporated by reference from the Company's Current Report on 8-K filed on July 28, 2003.

(2) Incorporated by reference from the Company's Registration Statement on Form S-l (No. 33-45446), declared effective by the Commission on March 17, 1992.

(3) Incorporated by reference from the Company's Registration Statement on Form S-8 (No. 33-66832) filed with the Commission on August 3, 1993.

(4) Incorporated by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 1994.

(5) Incorporated by reference from the Company's Registration Statement on Form S-8 (No. 33-80911) filed with the Commission on December 28, 1995.

(6) Incorporated by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 1995.

(7) Incorporated by reference from the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 1996.

(8) Incorporated by reference from the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 1996.

(9) Incorporated by reference from the Company's Current Report on Form 8-K filed on October 14, 1997.

(10) Incorporated by reference from the Company's Current Report on Form 8-K filed on January 26, 1998.

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(16) Incorporated by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2002.

(17) Incorporated by reference from the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2003.

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(19) Incorporated by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2003.

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(21) Incorporated by reference from the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2004.

(22) Incorporated by reference from the Company's Current Report on Form 8-K filed on September 15, 2004.

(23) Filed herewith.

Item 15 (c). None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

SCICLONE PHARMACEUTICALS, INC.

By: /s/ RICHARD A. WALDRON
Richard A. Waldron
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: March 15, 2005

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Alfred R. Rudolph and Richard A. Waldron, and each of them, his attorneys-in-fact and agents, each with the power of substitution and resubstitution, for him in any and all capacities, to sign this Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting to said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary, to be done in connection therewith, as fully as to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them, or their or his substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ ALFRED R. RUDOLPH, M.D. (Alfred R. Rudolph, M.D.)	Chief Operating Officer and Member of the Office of the President Principal Executive Officer	March 15, 2005
/s/ RICHARD A. WALDRON (Richard A. Waldron)	Chief Financial Officer and Member of the Office of the President Principal Executive and Financial Officer	March 15, 2005
/s/ IVAN HUI (Ivan B. Hui)	Director, Finance Principal Accounting Officer	March 15, 2005
/s/ JOHN D. BAXTER, M.D. (John D. Baxter, M.D.)	Director	March 15, 2005
/s/ EDWIN C. CADMAN, M.D. (Edwin C. Cadman, M.D.)	Director	March 15, 2005
/s/ JERE E. GOYAN, PH.D. (Jere E. Goyan, Ph.D.)	Chairman Emeritus	March 15, 2005
/s/ RICHARD J. HAWKINS (Richard J. Hawkins)	Director	March 15, 2005
/s/ ROLF H. HENEL (Rolf H. Henel)	Director	March 15, 2005
/s/ JON S. SAXE (Jon S. Saxe)	Director	March 15, 2005
/s/ DEAN S. WOODMAN (Dean S. Woodman)	Chairman of Board of Directors	March 15, 2005

SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS

SCICLONE PHARMACEUTICALS, INC.

Description	Balance at Beginning of Period	Charged to Costs and Expenses	Deductions	Balance at End of Period
Year Ended December 31, 2004				
Reserves and allowances deducted from asset accounts:				
Allowance for uncollectable accounts	$ 638,000	$ —	$186,000	$ 452,000
Year Ended December 31, 2003				
Reserves and allowances deducted from asset accounts:				
Allowance for uncollectable accounts	$ 638,000	$ —	$ —	$ 638,000
Year Ended December 31, 2002				
Reserves and allowances deducted from asset accounts:				
Allowance for uncollectable accounts	$ 638,000	$ —	$ —	$ 638,000

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31.2(23)	Rule 13a-14(a) Certification of Chief Financial Officer and member of the Office of the President.
32.1(23)	Section 1350 Certification of member of the Office of the President.
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(13) Incorporated by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2000.

(14) Incorporated by reference from the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2001.

(15) Incorporated by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2001.

(16) Incorporated by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2002.

(17) Incorporated by reference from the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2003.

(18) Incorporated by reference from the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2003.

(19) Incorporated by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2003.

(20) Incorporated by reference from the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2004.

(21) Incorporated by reference from the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2004.

(22) Incorporated by reference from the Company's Current Report on Form 8-K filed on September 15, 2004.

(23) Filed herewith.